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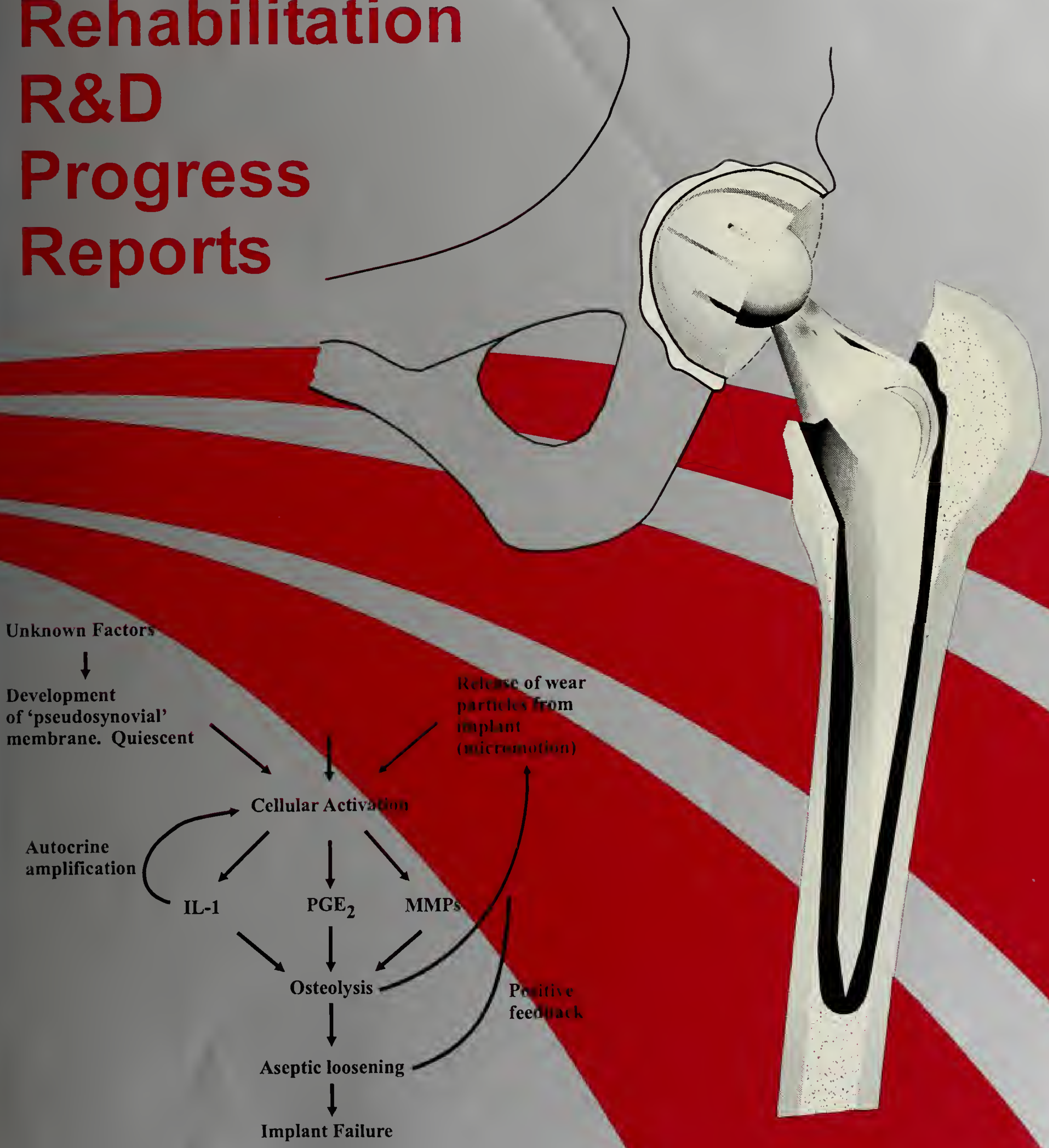
Department of
Veterans Affairs

Rehabilitation R&D Progress Reports



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Rehabilitation Research and Development Service

1997

ON THE COVER

A diagram illustrates the hypothetical chain of events proposed to occur in aseptic loosening of artificial total hip joint replacements. This VA-funded research, entitled, "Biochemical Analysis of Synovial Activation in Joint Dysfunction," is the work of Christopher H. Evans, PhD, VAMC, Pittsburgh, PA. Dr. Evans' hypothesis is: components of prosthetic hip joints shed wear particles. These interact with the surrounding tissues, provoking cellular activation. Activated cells then secrete high levels of Matrix Metalloproteinase (MMP), prostaglandin E2 (PGE_2) and interleukin-1 (IL-1), which provoke the local resorption of bone. This mechanically weakens the bone surrounding the implant, leading to aseptic loosening. IL-1 is likely to be an important autocrine amplifier of this process. A radical new approach to the problem of aseptic loosening of prosthetic joints is being investigated—the use of gene therapy.

This research is sponsored by the Department of Veterans Affairs, Rehabilitation Research and Development Service, John R. Feussner, MD, Chief Research and Development Officer, VA Headquarters, Washington, DC.

THE EDITOR

Cover design and production by Frank Vanni, Scientific and Technical Publications Section, Rehabilitation Research and Development Service, Department of Veterans Affairs, Baltimore, MD.

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The *Rehabilitation R&D Progress Reports* is published annually.

SUMMARY OF REQUIREMENTS

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2. Telephone number, fax number, and (if available) email address of the principal investigator.
3. Full name and address of the sponsoring organization(s), as well as the specific funded program. Include sponsor's telephone number and (if available) email address.
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Rehabilitation R&D Progress Reports

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I. Amputations and Limb Prostheses

A. General

[1] TECHNOLOGY TRANSFER OF A COMPUTER-AIDED SOCKET FABRICATION TECHNIQUE

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PURPOSE—A device and methodology have been developed for the automated production of sockets for artificial limbs. The device is intended to be used in conjunction with the computer-aided design (CAD) of sockets as a means for computer-aided manufacturing (CAM) of such sockets. In this continuation work, further testing of the device will be carried out, including the manufacture of three prototype machines to be placed in clinical settings. With successful outcome of the testing phase, commercialization of the device will begin.

METHODOLOGY—The evaluation and final development of the device will take part in two phases. In the first, various enhancements to the device are being tried and evaluated while at the same time the laboratory prototype of the machine is being used for remote manufacture of sockets for clinical fittings. In the second, three beta prototype machines will be designed, manufactured, and placed in clinical settings for on-site production of sockets.

The device uses a technique of plastic deposition to fabricate sockets. Plastic material is melted and extruded through a shape-forming die as a ribbon of melted material. A computer-controlled manipulator directs the flow of the melted plastic so that multiple layers representative of cross-sectional contours through the socket are deposited successively, one upon another.

PROGRESS—The chief focus for device enhancements has been mechanisms for cooling of the melted plastic after deposition. Various means of air cooling have been investigated, including the use of refrigerated air and building the socket in a cabinet enclosure. As an alternative, liquid cooling has also been explored. Liquid cooling has necessitated a slight reconfiguration of the machine and a redesign of the extrusion die, but shows promise in reducing the time required for socket fabrication (20–30 min as opposed to 1–1.5 hrs for a typical transtibial socket). Before liquid cooling can be applied to the routine fabrication of sockets, the mechanical strength of fabricated components must first be established.

Clinical trial of sockets has been ongoing with two sockets still in use after 2 and 3 years, respectively. In preparation for more widespread clinical socket evaluation, a relationship has been established with a clinical group heavily involved in CAD/CAM. Socket data files are being sent to our laboratory via email. The sockets are fabricated using our laboratory prototype machine and shipped, overnight, to the clinical facility.

Planning meetings have taken place to discuss the design and construction of the three beta prototype machines. Work on them is expected to be complete by April 1998 and the machines placed in Seattle, Chicago, and New York for clinical evaluation.

FUTURE PLANS—Mechanical testing of water-cooled socket fabrications will commence soon.

The remote-site socket evaluation trials using the laboratory prototype machine will be ongoing throughout the term of the project.

The on-site socket evaluation trials will commence on completion and distribution of the three beta prototype machines. As important as the evaluation of the sockets, the beta prototypes will give feedback on the viability, reliability and ease of use of the prototype machines in a clinical environment and by clinical practitioners. This valuable information will be incorporated into final product design and ultimate commercialization.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[2] CLINICAL AND LABORATORY STUDY OF AMPUTATION SURGERY AND REHABILITATION

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PURPOSE—The mission of the Prosthetics Research Study (PRS) is to advance the care for people having, or at risk of, limb loss. We address this broad mandate through fundamental prosthetics research, clinically implementing new technologies, and providing education in state-of-the-art techniques.

METHODOLOGY—In 1996-1997, PRS focused on three areas: the completion and validation of instruments for measuring outcomes of physical rehabilitation; the quantification of forces of lower limb prostheses in real-world settings using telemetered transducer instrumentation; and the electronic dissemination of research results and clinical practice guidelines.

PROGRESS—Validation of the Prosthesis Evaluation Questionnaire (PEQ), an easily administered questionnaire for comparing groups of prosthetic patients, was completed using data from 92 subjects, 60 of whom fulfilled all the requirements for the temporal stability measures. Ten scales were formed: 4 prosthesis scales, 2 mobility scales, 3 psychosocial scales, and 1 quality-of-life scale. Reliability tests showed that internal consistency was high as measured by Cronbach's alphas ranging from 0.73 to 0.89 (with one exception, 0.47); and test/retest was stable over 1 mo with intra-class coefficients ranging from 0.64 to 0.90.

The Gait Activity Monitor was used to measure the level of step activity of 62 subjects with diabetes and peripheral neuropathy, 17 of whom had lower limb amputation. Their average age was 67 years (range 41–85) years. Each subject was monitored for 2 consecutive weeks and completed the SF-36 questionnaire subsequent to monitoring. Self-selected walking velocity, fast walking velocity, and slow walking velocity were measured on each of three visits, during which subjects performed three trials at each walking speed in random order. The subjects averaged 3,288 steps per day (SD=2,064, maximum average=11,654, minimum=111). The average time with no step activity was 18.2 hours per day (SD=2.3, maximum=23.2, minimum=12.8). Average steps per day correlated significantly with three SF-36 scales: physical function ($r=0.419$, $p<0.01$), vitality ($r=0.3986$, $p<0.01$), and bodily pain ($r=0.2984$, $p<0.05$). Self-selected walking velocity did not correlate significantly with average steps per day; however, the difference between the fastest walking velocity and self-selected walking velocity did correlate significantly with average steps per day ($r=0.3011$, $p<0.05$).

The Prosthesis Force Transducer (PFT) was developed at PRS as a new means of quantitatively examining gait and comparing prosthetic prescription and alignment in real world situations. Data can be collected ascending stairs or walking down a hill, for example. This device allows remote monitoring of the axial force and anteroposterior and mediolateral moments at the socket-pylon interface during ambulation of persons with amputation. Although not as accurate or comprehensive as a ground reaction force plate, the device has the advantage of portability, low cost, and the ability to collect data from multiple steps. Study of data collected with the device may enhance our understanding of the important parameters in prosthetic design and fitting. Because it provides real-time feedback, the device also has possible clinical uses in alignment and gait training. This device has been bench tested, and data were collected from three subjects during the last year. Design problems have been identified and a more robust and accurate device is currently being built for further study.

Post-operative prosthetic treatment protocols were published on the world wide web and CD-ROM. The web site contains over 1,000 cross-referenced pages and has received an award from the MedSite index as an outstanding information resource for amputation and prosthetics. Another CD-ROM resulting from this research demonstrates dynamic alignment of the transfemoral prosthesis. It is currently being used on 6 continents, in 17 countries, 29 universities, 25 private clinics, 13 rehabilitation centers, 4 US government agencies, and by the degree programs of the University of Washington and the University of Texas. Prosthetists in the U.S. earn 4 continuing education credits using the program.

RECENT PUBLICATIONS FROM THIS RESEARCH

Amputations and prosthetics. Burgess EM, Boone DA, Gold JT. In: Dee R, Hurst LC, et al. editors. Principles of Orthopaedic Practice. 2nd edition. New York: McGraw-Hill; 1997. p. 345–76.

Design and pilot testing of the DVA/Seattle footwear system for diabetic patients with foot insensitivity. Reiber GE, Smith DG, Boone DA, et al. J Rehabil Res Dev 1997:34(1):1–8.

Lessons learned from a successful experience in technology transfer. Joseph AW, Boone DA, Mathews DE, Laing LS, Smith DG. Technol Disabil 1997;7(1/2):77–84.

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Gait Activity Monitor (Patent). Smith DG, Joseph AW, Boone DA, Borchers RE, Burgess EM. U.S.A. 5,485,402. 1996. Prosthetics Research Study.

[3] A SELF-ADAPTIVE DIGITAL PROCESSOR FOR PROSTHESIS CONTROL

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PURPOSE—The purpose of this project is to develop a microprocessor-based myoelectric controller for powered prosthetics. The digital controller calibrates itself automatically to the user's myoelectric signals and has the programmability to allow a broad range of control strategies. In addition to allowing persons with amputation to try out a variety of options without the need for calibration, the autocalibrating controller will accommodate changes in the inputs over the short and long term.

PROGRESS—A controller that can be used by users of transhumeral and transradial prostheses who wish to control two powered devices, such as an electric hand and an electric wrist rotator, has been developed. The original design, based on an industrial controller, has been replaced by a custom design based on the PIC16C84 microprocessor. The new controller is still small enough to fit inside VASI's VV5-9 electric hand and consumes very little power (approximately the same amount as the Otto Bock electrodes commonly used in prostheses) and has enough memory and speed to be able to implement virtually any commercially available control strategy. Production-grade prototypes of the controllers have been produced.

Graphical software for programming the microcontroller has been written for use with Windows 3.1. Data from this program are linked to the microcontroller through the computer's printer port, allowing a prosthetist and client to customize the controller. Seven of the microcontrollers have been dispensed to two children with bilateral transhumeral congenital limb deficiencies. Evaluation and clinical follow-up has shown that the controllers are reliable and flexible enough to meet a wide range of user needs.

FUTURE PLANS—In collaboration with the industrial partner for this project, VASI, a manual and a marketing and training plan for the microcontroller are being developed. Contractual arrangements with other prosthetic manufacturers for licensing the hardware and software used in this project are being pursued.

RECENT PUBLICATIONS FROM THIS RESEARCH

Programmable prosthetic controller. Kurtz I. Proceedings of MEC '97: issues in upper limb prosthetics; 1997, Fredericton, NB. p. 33.

B. Upper Limb: General

[4] GENERALIZED EPP POSITION CONTROLLER FOR ELECTRIC-POWERED UPPER-LIMB PROSTHESES

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PURPOSE—Today's externally powered prostheses use switch or proportional controllers with open loop velocity control. It has been shown that position control is superior to velocity control in positioning tasks. Furthermore, prosthesis control schemes that employ the body's own actuating and sensing systems seem to be incorporated more readily by prosthesis users. Such schemes may result in more subconscious control than other control schemes. Open-loop, velocity control cannot provide this sensory feedback. We believe that extended physiological proprioception (EPP) and EPP controllers as applied to externally powered prostheses is a way of achieving good control. To explore these ideas we developed an analog EPP controller and have gained considerable experience in the fitting of EPP-controlled prostheses. Shortcomings of our analog controller and the availability of low-power, low-cost microcontrollers led us to develop a microprocessor-based EPP controller. The primary reason for going to a microprocessor-based design is one of flexibility:it allows us to linearize the nonlinear characteristic of the force sensitive resistors (FSR) we use to transduce force into voltage. The analog device could not operate well at the low forces and excursions that were present in several of the experimental fittings.

METHODOLOGY—The microprocessor-based EPP controller is designed around the PIC16C73 microcontroller produced by Microchip Technology Inc. This microcontroller has been specifically developed for embedded applications where small space, low power, and versatility are of paramount importance and consists of a central processor unit (CPU), 5 A/D input channels, 2 PWM output channels, EPROM and RAM and 15 general I/O channels integrated onto a single chip. It sells for around US$8. For a clock rate of 100kHz with a supply voltage of 5 VDC, a typical value of the supply current is 40 μA when active and less than 1 μA when in standby.

In the control of an externally powered prosthesis, the controller and FSR form part of a force-actuated position servo-mechanism. The FSR sensor, along with signal conditioning electronics, transduces an applied force to a DC voltage in a form that an A/D channel of the microcontroller can read. This value is then output by the microcontroller on one of its pulse width modulated (PWM) outputs to a H-bridge that drives the DC motor of the prostheses until the force at the FSR transducer goes to zero. User parameters can be changed, via rotary dip switches or the appropriate analog potentiometers, to tailor the controller to a particular client.

PROGRESS—A working prototype has been developed, and we are currently in the process of transferring this initial prototype to a surface mount circuit board for further evaluation. The current system draws less than 0.5 mA at a supply voltage of 5 V.

RESULTS—This microprocessor-based controller has a much more linear response than the analog one. In addition, the parameters of the controller can now be changed independently of each other. Much of the functionality of the controller is implemented in software, giving us flexibility in configuring different topologies (i.e., uni- or bi-directional). This controller can be used in situations where only low forces and excursions are available, such as in the case of miniature tendon/muscle cineplasties. It can also be tailored for the force variations of a particular person during the course of using the prosthesis.

FUTURE PLANS—We envision using this controller as a building block for a multiple degrees of freedom prostheses. The next step is to test the controller clinically.

RECENT PUBLICATIONS FROM THIS RESEARCH

Microprocessor based EPP position controller for electric powered upper-limb prostheses. Bertos YA, Heckathorne CH, Weir RFff, Childress DS. 19th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; 1997 Oct 30-Nov 2, Chicago, IL.

[5] ESTABLISHING STANDARDS OF CARE: UPPER LIMB PROSTHETIC SERVICES

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PURPOSE—To date, no quality of care (QOC) standards have been developed to address the rehabilitative and ongoing support needs of persons with upper limb loss. This may be contributing to less-than-optimal outcomes for individuals who require diagnostic, therapeutic, and prosthetic services in order to function with maximal independence in the home, job, and other settings. The VA system, with its decades of service to persons with upper limb loss, may offer a model for quality of care that could be replicated in whole or in part by addressing the needs of people currently served through other systems, but there is presently no objective, systematic approach to documenting the strengths and weaknesses of its programs nor for determining their appropriateness for other populations.

METHODOLOGY—This project is designed to employ an expert approach, similar to the national consensus approach employed by CARF, to develop and test QOC standards for persons with upper limb loss. This can then be used to assess the efficacy of replicating the VA service approach in other settings. The Amputee Services Assessment Inventory (ASAI) has been developed and includes QOC standards and indicators as well as a protocol for self-assessment. A facility survey to be completed by program personnel evaluates the type and amount of treatment provided. A survey to be sent to persons with amputation from each participating facility also addresses the type and amount of services received, as well as outcomes measures and demographic information. This project will also increase the representation of VA-served persons with upper limb loss in the National Upper Limb Amputee Database developed by The Institute for Rehabilitation and Research (TIRR).

PROGRESS—The ASAI has been tested at three VA facilities (Houston, Palo Alto, and Seattle) and at five non-VA facilities (TIRR, Rehabilitation Institute of Chicago, University of Colorado, University of Michigan, and University of Virginia). Personnel at each facility completed a survey and coordinated a follow-up site visit by one of the investigators. Surveys will be now be sent to as many as 50 recent clients from each of participating locations.

FUTURE PLANS—The ASAI will ultimately be a tool for general use in ongoing monitoring and improvement of services for persons with upper limb loss. In the National Upper Limb Amputee Database, this data will be compared to that for individuals served by other systems to determine whether there are special needs or service issues in the VA population distinct from those identified for the general upper limb amputee population. Data analysis will examine upper limb amputee service delivery procedures, and recommendations for improvement will be made.

[6] THE WILMER COSMETIC PROSTHETIC PREHENSOR FOR CHILDREN

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PURPOSE—The standard split hook prosthesis is, despite its functionality, most often rejected by parents of a child with an upper limb defect because of the very poor and deterring outward appearance. The objective of this project is to develop a new prosthetic prehensor for these children that combines the functionality of the standard split hook prosthesis with an improved and appealing outward appearance.

METHODOLOGY—A shape study was performed to determine the outline of the new prehensor. The resulting outline is derived from the contor of a hand of a 4–6-year-old child. The length of the fingertips and the position of the rotating finger are approximately similar to a healthy hand. The connection to the forearm is harmonic and smooth. All mechanical parts, including the operating cable, are placed out of sight in the frame. Integrated within the frame is a lightweight friction wrist prosthesis. Also the frame is the pillar to the cosmetic cover made of flexible polyurethane resin. In this way, the outside of the prehensor is rugged and easy to maintain; the cover can be easily removed to access the mechanism; and the cover color can be chosen from a wide palette. Giving the cover a bright primary color emphasises the toy-like nature of the prehensor, thus advancing the acceptance and use of the prehensor by the child.

RESULTS—In collaboration with our clinical partners of the rehabilitation centres ''De Hoogstraat en Sint Maartenskliniek,'' the Netherlands, the new cosmetic prosthetic prehensor was clinically tested by 10 children. They all appreciate their new device greatly. It has not caused any negative reactions or strange associations. The children are delighted by the bright-colored appearance of the prehensor. Because of its smooth outline and the integration of the control cable, wear on clothing is reduced considerably. The mechanism of the prehensor has proved to be reliable but is rather cumbersome to assemble. Therefore, a new mechanism has been designed.

FUTURE PLANS—Laboratory and clinical testing of the new prehensor mechanism is expected shortly. Successful completion of these tests will result in commercializing the cosmetic prosthetic prehensor.

[7] CLINICAL COLLABORATION TO IMPROVE HIGHER-LEVEL UPPER-LIMB PROSTHETIC FITTINGS

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PURPOSE—Persons with higher level arm amputations (through or proximal to the elbow) and with bilateral arm amputations represent a relatively small proportion of prosthetic clients. Consequently, there is not the opportunity for developing a broad empirical foundation to guide clinical practice. Without guidelines, based on documented success in restoring function, it is difficult, at best, for clinicians to develop fittings with any degree of confidence in the outcome.

Our goal is to promote and develop principles and guidelines for improved higher-level and bilateral upper-limb prosthetic fittings. Toward that goal, we are using our research and development capabilities in direct collaboration with a clinical service program in prosthetics, the Prosthetic/Orthotic Clinical Services Department of the Rehabilitation Institute of Chicago (RIC). The RIC Amputee Program has a national and international reputation and, consequently, receives referrals of persons with high-level amputations from across the United States and abroad.

METHODOLOGY—Over the past 10 years, we have collaborated in the treatment of 36 persons with bilateral arm amputation. Of these, 23 had sustained high-level bilateral limb loss. To maximize manipulative capability and provide complementary function, we have developed prosthetic designs that incorporate multiple actively positioned components in a hybrid configuration (combining body- and electric-powered components). In general, the dominant prosthesis of this bilateral pair is configured with all mechanical, positive-locking, cable-actuated components while the nondominant side incorporates either all electric or hybrid componentry.

PROGRESS—We are continuing work on a manual for prosthetists describing the design and implementation of the four-function control system for body-powered transhumeral prostheses. In this configuration, a mechanical elbow, a wrist rotation unit, a wrist flexion unit, and a voluntary-opening split hook prehension device are arranged so that a single control cable can be used to position any one of the four components. The elbow and wrist components are held in place by mechanical locks. Whenever one of these components is unlocked, action on the control cable affects the position of that component. When all three components are locked, action on the control cable operates a voluntary-opening split hook prehension device. We have had considerable success with this configuration and believe, with the support of users' comments, that the extension of the user's physiological proprioception via the control cable reduces the mental effort required in positioning and using the prosthesis.

We are also continuing to work with Milo Collier and Associates (MICA) Corp. (Longview, WA) and Liberty Technology (Hopkinton, MA) on evaluation and refinement of the MICA locking shoulder joint, the only commercial locking shoulder joint available. We have been a proponent of locking prosthetic joints in preference to friction-type joints. A locking shoulder joint maintains the prosthesis as a rigid extension of the user's body when the user wants to exert forces on an object or support a heavy object. Additionally, this particular joint enables a person to handle and act upon objects above the level of the head, a significant functional advantage.

Since the introduction of the shoulder joint in the early 1990s we have assisted the RIC Prosthetic/ Orthotic Clinical Services Department in fitting nine of the joints. We have made modifications to the joints, especially the locking actuator, to improve its operation. All modifications have been communicated to MICA and Liberty Technology. We also continue to monitor the users' experiences with the joints and relay that information as well. In addition to the MICA/Liberty Technology joint, we are evaluating a new locking shoulder under development by Cypromed (Ottestad, Norway).

FUTURE PLANS—We plan to complete the manual for prosthetists describing the design and implementation of the four-function control system and to disseminate our experiences with locking shoulder joints.

RECENT PUBLICATIONS FROM THIS RESEARCH

Management of the person with high-level bilateral arm amputations. Uellendahl JE, Heckathorne CW. Proceedings of MEC '97: issues in upper limb prosthetics (myoelectric controls/powered prosthetics symposium); 1997, Fredericton, New Brunswick. p. 17–20.

[8] LIFE INTERFACE FOR CLOSED LOOP CONTROL OF ARTIFICIAL LIMBS

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Sponsor: *National Institute of Neurological Disorders and Stroke of the National Institutes of Health, Bethesda, MD 20892*

PURPOSE—Our long-term aim is to develop an interface to connect artificial limbs to the peripheral nerve stumps of persons with amputation. The purpose of this study was to investigate whether it is possible to selectively stimulate sensory neurons and record motor nerve activity, with the longitudinal intrafascicular electrodes (LIFEs) implanted in chronically transected nerves (>8 week duration).

METHODOLOGY—Subjects with chronic upper limb nerve injury and upper limb amputation undergoing elective surgery were invited to participate. LIFEs were constructed from a Teflon-insulated 25 μm Platinum-Iridium wire; 2.5 cm from its end is a 1 mm recording/stimulating zone. A 20 μm tungsten needle, attached to one end of the electrode, was used to thread this region through a 1 cm zone of a proximal nerve stump fascicle. A maximum of four LIFEs were implanted in four separate fascicles and exteriorized percutaneously. Nerve function was evaluated on 2 consecutive days postoperatively.

The subject was asked generate motor nerve activity by attempting to make movements of the missing limb (or dennervated muscles). These motor signals were channeled via a differential amplifier/filter to a loudspeaker, and via analog-to-digital converter to a DOS computer. The computer was programmed so that the position of a cursor was a direct function of the number of action potentials per unit time. By listening to audio sounds the subject selected the most appropriate movement that corresponded to a particular electrode. The subject was then asked to precisely control the selected movement and position a cursor in a randomly appearing target across the monitor.

The nature, intensity, and topographical location of referred sensations was assessed by having the subject report on the sensations elicited with different values of stimulating pulse width (50–500 ms), amplitude (1–100 μA) and frequency (50–500 Hz).

PROGRESS—Four subjects (two with amputation and two with chronic nerve transections) have been studied.

Pt-Ir LIFEs are stiff wires in comparison to nerve tissue, and this has resulted in potential electrode drift within a fascicle. A new type of Kevlar fiber-based LIFE has been developed, with stimulation/recording properties similar to the Pt-Ir electrode but 50 times more flexible. Preliminary studies indicate it is biocompatible.

PRELIMINARY RESULTS—Subjects were able to generate and control motor nerve activity associated with missing/dennervated muscles after a short period of training. Localized referred sensations of touch and proprioception to the damaged nerve territories of the upper limb could be elicited by electrical stimulation of fibers in the proximal nerve stump. Subjects reported intensities of sensations that varied with logarithm of frequency of afferent nerve stimulation.

FUTURE PLANS—Once acute studies have been completed, we plan to study these subjects with 1- and 6-mo LIFE implants, respectively. Effects of chronic nerve stimulation, learning, CNS plasticity on the long-term efficacy of providing sensory feedback and motor control with the LIFE interface will be evaluated. These recording/stimulation data will be used by engineers at the Center for Engineering and Design, University of Utah, to design sensors and control systems for a neurally controlled artificial arm. Signals from the LIFE interface will then be channeled to the neuroprosthetic arm to evaluate how well subjects can execute closed-loop control.

RECENT PUBLICATIONS FROM THIS RESEARCH

Metallized polymer fibers as leadwires and intrafascicular microelectrodes. McNaughton TG, Horch KW. J Neurosci Meth 1996;70:103–10.

[9] AN INVESTIGATION INTO THE EFFECTIVENESS OF FITTING POWERED UPPER LIMB PROSTHESES: THE UNB EXPERIENCE

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Sponsor: *University of New Brunswick Research Fund*

PURPOSE—In the fall of 1981, the Institute of Biomedical Engineering (IBME) at the University of New Brunswick (UNB) opened a myoelectric fitting center, with the first client fitted January 1982. Since then, over 127 clients have passed through this center.

The overall goal of this retrospective study was to address two simple questions: What percentage of clients are still wearing and using a powered upper limb prosthesis? If a client is presently not wearing a powered prosthesis, then what are the reasons?

In addition, an attempt was made to gather information regarding basic wearing patterns for those clients who are still using a powered prosthesis.

METHODOLOGY—The study was conducted in three stages: Clients not seen as the center in the past 3 yrs were contacted by mail and asked to complete a written questionnaire. As clients return to the center for refitting, repair, or re-evaluation, the same questionnaire was completed. Clients missed by the first two steps were contacted by telephone and interviewed using the questions from the questionnaire. The questionnaire consists of only two pages: one for wearers and one for nonwearers.

RESULTS—Of the clients seen at UNB over the last 14 yrs, approximately two-thirds were below the age of 18 when first fitted. As our primary thrust is in powered upper limb prosthetics, most of these prostheses (~87 percent) have been myoelectrically controlled. From the active case load (i.e., those clients who have visited the center in the last 36 months) 90 percent are still using their prostheses. For the inactive group, only 35 percent reported that they continued to wear their prostheses.

In the wearers group, 48 percent used a powered prosthesis exclusively, and 14 percent used a nonpowered device exclusively, and 38 percent reported using more than one type of prosthesis. This tends to reflect the common usage of sports limbs designed for specific activities and cosmetic prostheses for social occasions.

The responses relating to patterns of prosthesis use were split into 'where? ' and 'how long?'. It was found that 83–87 percent of the wearers reported using their prostheses at work, school, or social events, with 69 percent responding that they used their prostheses only for recreation and play activities; 44 percent wore their prosthesis for all activities. About a third of wearers tend to use their prosthesis less on the weekends than through the week.

A substantial proportion, 17 percent, reported wearing their prosthesis all day (>12 hrs), and 66 percent indicated they use their prosthesis >4 hrs per day. Consequently, approximately 83 percent wear their prostheses >4 hours per day. The remaining 17 percent tend to use their prostheses only for specific tasks which they would not otherwise be able to complete.

In the nonwearer group, 88 percent reported that they got along well without it. Half of them also indicated that the prosthetic limb was uncomfortable, while the other half responded that the prosthesis did not compare to the function of their sound limb.

IMPLICATIONS—It is the view of the authors that the fitting of powered upper limb prostheses is effective. This is substantiated by the finding that overall, 76 percent of clients contacted are still wearing their prostheses and of those, 83 percent wear their prosthesis for more than 4 hours per day.

[10] DEVELOPMENT OF A MULTIFUNCTION MYOELECTRIC CONTROL SYSTEM

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Sponsor: *University of New Brunswick Research Fund*

PURPOSE—We seek to develop a myoelectric control system that is easy to operate, yet provides control of many independent prosthetic limb functions.

METHODOLOGY—During the initial 24 mo of the project, we determined the specifics of a new control strategy, based on the recognition of patterns in the myoelectric signal. This work involved computer simulations of control schemes using various waveform features to determine which provided the most information to the artificial neural network classifier. The results indicated that a control scheme that used information from two myoelectric channels provided a richer feature set and improved system performance at the expense of increased system complexity over the original single channel system. As well, the additional myoelectric channel gives the system the ability to operate as a degree-of-freedom (DOF) controller as opposed to the more restrictive state controller of the original design.

The resulting control scheme uses information collected from the person with amputation to train a pattern classifier to recognize his or her specific contraction patterns, using features extracted from the first 200 ms of myoelectric activity following the initiation of a contraction to determine the intent of the person. The classifier matches this feature set with the sets obtained during the initial system calibration. The closest match is used to select which device (hand/elbow/wrist) is to be controlled. Control of this device continues until the signal level returns to a predetermined low level.

Pattern classifiers based on alternate neural network structures were also investigated to determine the feasibility of implementing a classifier based on continuous data. In particular, a dynamic feedforward network which incorporates memory in the form of an FIR filter structure for each network weight has been shown to be appropriate for these transient myoelectric signals. Work is continuing with the goal of finding alternate feature representations and neural network structures that give continuous recognition of the raw myoelectric signal. The advantage of such a scheme is that system delay is reduced, compared to the present scheme that uses features from time-averaged data.

During the second or current stage of the project, a microprocessor-based multifunction control system has been designed that incorporates results from this project as well as the latest advances in electronic hardware. The current prototype is the result of several design iterations which have reduced the size and power consumption of the control system. The current device uses surface-mount technology on multilayer circuit boards to achieve a size of 3.8×6.35×1.27 cm and can be built into the prosthetic arm. The device operates on standard 6 V NiCad batteries drawing approximately 40 mA.

FUTURE PLANS—Clinical trials with this control system have begun at our fitting center in Fredericton. Arrangements have also been made with Hugh Steeper Ltd. (UK) to do test fittings on several of their current clients in their Roehampton and Birmingham clinics.

[11] THE INCORPORATION OF A SLIP-SENSING, CLOSED-LOOP CONTROL SYSTEM INTO A MYOELECTRIC PROSTHETIC HAND

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Sponsor: *Variety Ability Systems, Inc.; Natural Sciences and Engineering Research Council of Canada, Ottawa, ON Canada K1A 1H5*

PURPOSE—The current control scheme of the myoelectric prosthetic hand is of an open loop type. Myoelectric inputs (electromyographic, or EMG) from the user are translated to output by the motor, with no error feedback. This project proposes a method for integration of a supplemental, closed-loop controller to the prosthetic hand. Specifically, a slip control scheme will be incorporated into the hand so that the grip will tighten on an object as incipient slip is detected. In a conceptual sense, the supplementary controller will act as the hand's subconscious, much like the reactionary responses of an enervated hand.

METHODOLOGY—Piezoelectric ceramic sensors were built into two of the fingertips of a VASI (Variety Abilities Systems, Inc.) 5-9 child's prosthetic hand. Piezoelectric materials are defined by their unique ability to translate mechanical disturbances into electric signals without a directional bias. Such a robust sensor was deemed desirable for the rugged and unpredictable environment that a prosthetic hand is likely to experience. Electric signals from the sensors are filtered and brought into the digital domain for signal comparison and subsequent slip detection. Output from the digital algorithm controls the hand's motor when the myoelectric system is inactive.

PROGRESS—The initial slip controller design was updated to a more portable form, and testing of the slip sensing system is impending. The myoelectric hand, with the standard 1100:1 geared motor, is run off an external 6 V battery for convenience, while the slip control algorithm is executed in a desktop computer. This nonmobile version is sufficient for testing the feasibility and benefits of the system.

FUTURE PLANS—Control of a highly geared motor is imprecise and cumbersome, at best. Meaningful motor control from the digitally based slip detection algorithm can be designed in such a way, however, as to elicit the desirable response times with a practical level of accuracy. This system is currently being designed and will shortly be implemented and tested.

The future will see this project exploring other aspects such as material interfacings on the sensor surface, and the final miniaturisation of the controller for a compact fit into the prosthesis.

[12] VV 2-6 PROSTHETIC HAND ENHANCEMENTS: COSMETICS AND FUNCTION

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Sponsor: *Variety—The Children's Charity*

PURPOSE—The aim of this project is to improve the cosmetic appearance and function of the VASI 2-6 hand (for children 2 to 6 years of age).

PROGRESS—The bulk in the palm area has been reduced through redesign of the hand body and cover profiles. This significantly improves the hand's cosmesis. New tooling for production of the hand body and cover have been completed and were being tested in the first quarter of 1997; production parts should become available in the second quarter of 1997.

Another improvement, the coupling of the ring and baby fingers to move together with the other fingers when the hand closes has been prototyped. Tooling and final production details are pending.

A third improvement, the incorporation of pliable tips on the fingers and thumb, are in the design and prototyping stage. Evaluation of these finger tips is anticipated in the second half of 1997.

FUTURE PLANS—We plan to continually evolve the cosmesis and functionality of the VASI hands to meet the needs of our clients and to offer leading prosthetic technology in the marketplace.

B. Upper Limb: Transradial

[13] VOLUNTARY-CLOSING HAND PROSTHESIS

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Sponsor: *Delft University of Technology, Delft, The Netherlands*

PURPOSE—The objective of this project is the design of a voluntary-closing hand prosthesis for persons with unilateral transradial amputation. The prosthesis must have pleasant cosmetics, good wearing comfort, and easy operation.

METHODOLOGY—In voluntary-closing devices, operating force corresponds to pinching. To make full use of the feedback potential of this working principle, the prosthesis operating mechanism should transfer the actual pinching force to the operating member as purely as possible. Therefore, friction should be absent, and the counteraction of the cosmetic covering compensated for. Among the practical problems to overcome, the opened resting position, which is generally not acceptable for cosmetic as well as practical reasons, seems to be the most important one.

PROGRESS—This research is divided into several projects.

1. Assessment of glove characteristics. Glove stiffness and hysteresis are dependent on the trajectory

of finger movement. A cosmetically acceptable minimum hysteresis thumb trajectory was assessed. Hysteresis was reduced by 65 percent, stiffness by 50 percent.

2. Compensation of glove forces. The elastic component of the glove counteraction can be statically balanced by a compensation spring mechanism. A systematic methodology for the type synthesis of statically balanced spring mechanisms was set up.
3. Reduction of friction. From a sister project, the design of laparoscopic forceps, we gained experience in designing rolling link mechanisms. Mechanical efficiency was increased from 30 to 96 percent.
4. Optimal feedback. No new measurements are performed. When the prototype is ready, experiments are planned to compare the dexterity of voluntary closing and voluntary opening hand prostheses.
5. Operating pattern. A questionaire was held among Dutch rehabilitation teams on the question of the operating scheme of a voluntary-closing hand with a closed resting position; results are being processed.

PRELIMINARY RESULTS—A prototype of a voluntary-closing hand prosthesis is under construction. It incorporates a low friction mechanism, while special attention is paid to the pivot of the elbow control lever. The thumb moves along its optimal trajectory, of which the elastic counteraction is reduced by a glove compensation mechanism.

FUTURE PLANS—We intend to extend the theory and design of statically balanced spring mechanisms to include nonlinear springs. The reliablity and durability of several low-friction mechanisms and compensation mechanisms will be tested. The prototype of the hand prosthesis is to be finished and evalulated in a laboratory setting.

RECENT PUBLICATIONS FROM THIS RESEARCH

Design of spring force compensation systems. Herder JL. Mech Machine Theory. In press.
Methods for reducing energy dissipation in cosmetic gloves. Herder JL, Cool JC, Plettenburg DH. J Rehabil Res Dev. In press.

[14] BODY-POWERED TODDLER HAND

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PURPOSE—We seek to develop an improved body-powered hand for toddlers one to four years of age. The primary design goals are for an affordable hand of acceptable cosmesis to provide useful grasp for children at play. Minimal energy input should be required to use the hand.

METHODOLOGY—Exploration of several hand design strategies and different methods of harnessing a child's energy has brought the project focus to center upon two designs. Neither requires a cable for activation but rather makes use of the energy of the opposing hand to insert objects. The two designs embody different balance points between form and function. One design aims for life-like appearance while the other departs from anatomical imitation to look ''fun'' and requires no cosmetic covering. Both designs are developing in close collaboration with the medical and technical staff at the Child Amputee Prosthetics Program at the Shriners Hospital of Los Angeles. A laboratory test of grasp performance helps with preliminary assessment of new designs. A parent preference study will focus on the decision-making process involved in selecting a prosthesis for the child. Prototypes are field-tested and evaluated for performance, reliability, and cosmetic acceptability once lab results are satisfactory. The design principle is to keep concepts and components as simple and rugged as possible, and small-lot manufacturing costs low.

PROGRESS—Research this year has been devoted to the following tasks:

New Hands

Prototypes of two of the most promising hand designs from Year 1 are now built and field testing has begun. The first design, dubbed the Easy-Feed hand, is a metal endoskeleton structure fitted with compliant foam, silicone, and a cosmetic glove covering. The shape approximates the hand of a 2-year-old. Its purpose is to offer acceptable cosmesis and grasp function to the youngest toddlers without need of a cable harness. The primary design feature lies in utilizing the power of the child's sound hand to insert and remove objects. This accords with the natural usage pattern of the prosthesis by a child with unilateral limb deficiency as a nondominant limb serving the function of holding objects for use rather than picking them up. As the toddler develops more strength and cognitive skill, the hand converts to cable-actuation and functions in either voluntary opening or voluntary closing mode.

The second prehensor design, dubbed LN, is also cable-free and comprises a colorful exoskeleton structure requiring no covering. Instead of striving for precise human-like appearance, the design favors fun and function and includes two thumbs for a more versatile grip. A built-in clutch mechanism keeps the thumbs closed around objects until released via a spring-loaded wrist.

Clutch Module

This optional unit may be used with a cable-activated hand to provide an automatic safety brake. When the child relaxes the harness-input cable, the clutch engages automatically to keep the hand closed around an object. When the cable is again pulled, the hand opens to release the object. For safety, an override spring permits object removal.

Flexible Gloves

Up to half of the effort expended by a child to open a prosthetic hand goes into the deformation of the stiff PVC cosmetic glove. To minimize energy demands placed on the toddler, some flexible glove designs are in development, exploring both new materials and different shell geometries.

Laboratory Testing and Prediction of Grasp

A lab test has been developed to help evaluate grip performance of prosthetic hands. A variety of children's toys are used to estimate the grasp capabilities of each new design before testing on children. Strengths and weaknesses are measured by applying forces to the objects corresponding approximately to conditions of actual use.

Which Hand is Best for My Child?

A parent preference study protocol has been developed to explore tradeoffs acceptable to parents weighing hand appearance with function. Further, parents will use a variety of prehensors to perform the same tasks as their youngsters, for example playing with blocks, tricycles and baseball bats. A hands-on test may influence a parent's choice.

RESULTS—The first Easy-Feed hand has a large opening grasp of 3 in span and provides a minimum pinch force of 1 lb. (adjustable). Objects may be inserted and removed by pushing and pulling. The LN hand has been produced in both colorful plastic and wood. Its unique geometry provides stable cylindrical grasp. Preliminary testing indicates openness of some parents and children to try this alternative design. Its operation requires cognitive skills beyond that of the youngest toddlers. Manufacturing costs and durability of both designs require further attention.

Gloves employing a compliant elastomer have been fabricated and field tested. While offering grip performance advantages over PVC and being easier to apply and remove, durability is a concern. Gloves of conventional vinyl material with altered geometries appear more promising in the short term, incorporating gussets, pleats and wrinkles to enable a large opening with reduced resistance. Cosmetic acceptability will be evaluated in clinic.

Lab testing of grip performance appears a helpful guide for efforts to enhance function. It enables some qualitative and quantitative comparison among different grasp geometries and compliant surfaces. Early evaluation should increase the value of each clinical trial.

FUTURE PLANS—Clinical testing and refinement of both hand designs will proceed. The clutch module will be made smaller and tested, and gloves of various configurations molded and evaluated for function and cosmesis. The grip test will be compared with clinical trials, and the parent study commenced. Collaborations with commercial manufacturers of prosthetic hands will be strengthened.

[15] A MULTI-DEGREE OF FREEDOM PROSTHETIC HAND FOR CHILD USER

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Sponsor: *Natural Sciences and Engineering Research Council of Canada, Ottawa, ON Canada K1A 1H5*

PURPOSE—This project involved the development of a powered multifunctional hand prosthesis for children and young adults, focusing on modifying the current pincer type prosthesis. The new design should allow for better orientation of objects to be held, improve stability of the objects, and minimize compensatory motions during the prehension phase.

PROGRESS—The three most frequently used grasping patterns, tip grip (precision handling: writing and handling small objects), palmar grip (power grip: for larger or round objects like bike handles or balls), and lateral grip (used to hold flat objects such as keys) were defined, along with the motions of the fingers and the thumb related to these grips. Following verification of the design using computer simulation, a prototype hand was manufactured and tested by a 12-year-old subject, contrasting its performance with that of his currently worn hand. The subject performed all tasks equally well with both hands. However, with the new hand, compensatory body movements were minimized, and a larger variety of objects could be held with increased stability than with his current hand.

FUTURE PLANS—Concepts developed through this work will be incorporated into revised hand designs for VASI.

IMPLICATIONS—The hand appears to provide the user with significantly improved function when compared with currently available prostheses. A challenge beyond the scope of this project is the development of a flexible but durable glove.

[16] RECENT ADVANCES IN THE DEVELOPMENT OF PARTIAL HAND PROSTHESES

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Sponsor: *University of New Brunswick Research Fund*

PURPOSE—Recently, two persons have presented with partial hand amputations in which the digits and distal ends of the metacarpals were missing, but the thumb was intact. One of these was a child with a congenital absence and the other an adult with loss of digits through a farming accident.

The child has been fitted with two different systems, the first based on the motor and finger group of an Otto Bock size 5 Electrohand 2000, and the second based on our own, in-house, design. The adult has been fitted with mechanical fingers having multiple locking positions. The prostheses have been used extensively.

METHODOLOGY—The original fitting of the child was accomplished by building up a powered finger unit from the motor and finger block of the Otto Bock hand. The hand's wrist attachment, thumb, and related linkages between the thumb and fingers were removed, leaving a unit approximately 1.2 mm in diameter and 45 mm long. This was then laminated to a socket that left the thumb exposed and free to move. Electrodes were placed over the thumb flexors/adductors and the extensors/abductors so that as the thumb was flexed or extended, the finger group mimicked the motion. The control method worked well, and the action of fingers and thumb together gave a natural grip that was easy to learn to control.

The child was an enthusiastic and active user, and eventually the modifications led to failure of the drive. This is in no way a criticism of the hand, which was being used in a way for which it had simply not been designed.

We have built a second unit around a MicroMo 1319 electric motor and a 246:1 gearbox. The unit is built so that a sleeve holding the fingers is attached to the output shaft of the gearbox, projects back over the gearbox housing, and rides on a pair of Teflon bushings. The fingers are brass rods inserted into a projecting mounting block on the sleeve. The casing, in which the motor and gearbox are mounted, is laminated into the prosthesis. The leads from the motor are brought out the end of the unit and two electrodes, a digital bridge, and a remote 6V battery pack complete the system. The range of finger motion of approximately 60°, and opening and closing for the unloaded unit is approximately 200 ms. The stall torque is 9 in-lbs. The unit was provided with a rubber bumper system to cushion the end points of the finger travel.

In both devices, the glove to cover the fingers has the thumb cut out and required a substantial amount of stretching to allow the fingers full range of motion.

The adult mechanical hand was built to provide a robust device for a farmer. It consists of a sleeve and core rather than the motor unit described above. All four fingers are attached to the core, which also has a three position lock activated by pressing on a button through the cosmetic cover. The fingers have a range of approximately 90° with the locked positions being with the fingers fully extended, partly flexed, and flexed to 90° so that the thumb can come into contact. The fingers were covered with an Otto Bock inner hand shell and then covered with an outer cosmetic glove with the thumb removed. The finished prosthesis ends just distal to the wrist, allowing relatively unrestricted wrist motion.

RESULTS—Both the powered and mechanical hands have had active use in the field. The original child-sized, powered prosthesis was used actively until it failed mechanically. The second model continues in the field.

FUTURE PLANS—Both fittings have been successful, and the mobile fingers have worked well and have been very functional for this particular form of partial hand amputation; both designs can be scaled up or down to accommodate different hand sizes.

[17] A MULTIFUNCTION CONTROL SYSTEM FOR POWERED UPPER EXTREMITY PROSTHESES

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Sponsor: *None listed*

PURPOSE—This research project is involved with the development of a multifunction control system for upper extremity prostheses for children and young adults. The focus of this work is to examine the input to the classifier, in order to qualitatively determine the choice most likely to yield a working system.

METHODOLOGY—There has been a great deal of investigation into classifiers/pattern recognition techniques for the purposes of discriminating prosthetic function. However, previous research has focused on development of better classification schemes, and the choice of input has not been considered in detail. Various parametric representations of the myoelectric (ME) signal have been chosen as input for these classifiers either for simplicity's sake, or because it was hypothesized that they would yield a better result. However, no comparison of their relative merits has been conducted. Furthermore, clinical implementation of the classifier was seldom considered, and investigations have almost always been conducted in controlled situations only, which does not allow for the large variations in the ME signal under normal conditions of use (i.e., loading, fatigue, residual limb movement). Therefore it is the purpose of this work to examine the ME signal produced under various conditions of use, and analyze it in order to determine the optimum parametric form for use as an input to a classifier. Furthermore, this choice of input will then be tested in order to determine if much improvement can be found using a conventional classifier (e.g., neural network) from previous works.

PROGRESS—Test subjects consisting of individuals with transradial amputation and congenital limb deficiencies, will be asked to perform six different types of contractions (the contractions will be different for each individual, depending on personal ability) under controlled conditions, loading, and during motion of the residual limb. The raw ME signals will be recorded from two electrode sites, corresponding to those used for each person's current prosthesis. The data will then be represented using as many spatial and spectral parameters as possible, and various sizes of time windows. Standard statistical packages will then be used to cluster the data. Since the intent of each contraction is known a priori, the success of each representation can be gauged, based upon the number of points incorrectly clustered, and a measure of how far away each misclassified point is from its correct cluster. In addition to the overall performance of each parametric representation, this test will yield information about which representations cluster the best for each particular contraction type. It may then be possible to use a combination of parameters in order to achieve the highest levels of discrimination. Data recording is tentatively scheduled for summer 1997, subsequent to ethical approval and equipment set-up. Analysis of the data will then be conducted.

IMPLICATIONS—The work is expected to yield the best parametric form of the ME signal for use in classification problems. Given this ''best'' input, any classifier can be tested in order to determine its optimum effectiveness.

C. Lower Limb: General

[18] GAIT MECHANICS OF THE PARTIAL FOOT AMPUTEE

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PURPOSE—Diabetic pathology often requires an amputation; however, surgical advances are permitting preservation of more of the forefoot. This maintains the integrity of the leg, but changes the weight-bearing distribution of the foot and may lead to ulceration of the heel or residual foot segment. Clear understanding of the biomechanics of walking following partial foot amputation may identify criteria for surgical, orthotic, and prosthetic management that will enhance the durability of the residual foot. The purpose of this research is to: 1) compare the gait biomechanics of toe, metatarsal, ray, Lisfranc and Chopart level amputations with normal function; 2) analyze quantified pressure patterns of both residual and sound limbs; 3) determine the effects of amputation level on sound limb function; and 4) assess the efficacy of prosthetic/orthotic devices in altering gait characteristics of those with partial foot amputations.

METHODOLOGY—Comprehensive gait analyses are being conducted, including collection of kinematic and kinetic data, electromyographic activity in the main extensors in both the residual and sound limb, and foot pressure patterns. All of these data are being assessed with and without footwear. Additionally, the isometric strength of the major extensor muscle groups in each leg is being tested.

PROGRESS—To date, 36 individuals with partial foot amputations have participated in this study (15 toe, 10 metatarsal, 9 ray, 1 Lisfranc, and 1 Chopart level). Additionally, the reliability and validity of the Novel Pedar data collection system for foot pressure analyses has been established, using 10 individuals without foot pathology.

PRELIMINARY RESULTS—Comparisons were made of kinematic and strength patterns between six individuals with toe, and six with metatarsal, amputations during barefoot free walking conditions. Mean walking velocity was reduced for both toe and transmetatarsal amputation groups relative to normal (59.2 and 51.6 percent of normal, respectively) due primarily to decreased stride length (69.8 and 58.8 percent of normal, respectively). Cadence also was reduced (toe=83.6 percent; metatarsal=86.2 percent of normal). However, these between-group differences were not statistically significant.

Statistic analyses of ankle motion profiles revealed significantly less peak ankle dorsiflexion in terminal stance for those with metatarsal amputation than in those with toe amputation (metatarsal=6.8°; toe=10.9°; $p<0.05$). Additionally, peak dorsiflexion in terminal stance occurred significantly later for those with metatarsal amputation (metatarsal=53.2 percent of gait cycle, toe=49.0 percent of gait cycle, $p<0.05$).

Substantial decreases in muscle strength from normal were found in sound and residual limbs for both groups, although no statistically significant differences between groups were noted. Strength deficits were most pronounced in the residual limb ankle plantar flexors of both groups when compared to normal (metatarsal=30.1 percent of normal, toe=39.1 percent of normal).

The absence of a forefoot rocker in the metatarsal group compromised the ability of these individuals to progress forward, as evidenced by reduced peak ankle dorsiflexion in terminal stance. This, in combination with diminished calf strength, caused decreased velocity and stride length.

FUTURE PLANS—Data collection and analyses are ongoing with a target number of 70 participants. Specifically, the weight-bearing pressure patterns of both the residual and sound limb are being investigated to determine the efficacy of prosthetic inserts and footwear in preventing ulceration. The impact of partial foot amputation of the limb-loading patterns of the sound leg is also being analyzed.

RECENT PUBLICATIONS FROM THIS RESEARCH

Determination of Novel Pedar masks using Harris mat imprints. Bontrager EL, Boyd LA, Heino JG, Mulroy SJ, Perry J. Gait Posture 1997;5:167–8.

The reliability and validity of the Novel Pedar system of in-shoe pressure measurement during free ambulation. Boyd LA, Bontrager EL, Mulroy SJ, Perry J. Gait Posture. 1997;5:165.

[19] A STUDY TO DETERMINE THE BIOMECHANICAL EFFECTS OF SHOCK-ABSORBING PYLONS

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PURPOSE—Vertical shock pylons are designed to function as shock absorbers for lower-limb prostheses by attenuating forces associated with walking and high-impact activities, such as running and descending curbs and stairs. Many persons with amputation seem to show a clear preference for walking with these devices, but the function of the devices during gait and the influence on the resulting pattern of walking is unclear. The purpose of this investigation is to perform mechanical analyses of commercially available vertical shock pylons to gain a better understanding of their function during walking.

METHODOLOGY—We are investigating three vertical shock pylons: the Flex Foot Re-Flex Vertical Shock Pylon (Flex), the Ohio Willow Wood Stratus Impact Reducing Pylon (Ohio), and the Seattle AirStance Pylon (Seattle). Static and dynamic testing of these devices, using a specially designed testing apparatus with attached mass, will permit calculation of the damped natural frequencies, spring constants, damping coefficients, and damping ratios, and indicate their abilities to store and return energy. Static testing allows the force versus deflection characteristic of each device to be determined. Creep rate is also measured. The dynamic testing involves step loading and unloading the vertical shock pylons while measuring the resulting axial displacement.

The Flex consists of graphite telescoping tubes in parallel with a carbon fiber compression spring for shock absorption and energy return. There are a total of nine spring stiffnesses available, accommodating subjects weighing anywhere from 45 to 147 kg. We are testing five of spring stiffnesses, evenly distributed across the range of stiffness values. Each stiffness is being tested with three weights that represent the high, low, and mean values of the manufacturer's recommended range of allowable body weights for that particular spring.

The Ohio consists of a viscoelastic compression ring seated within a telescoping housing. The ring is compressed with applied load, and returns to its original shape as load is removed. There are five stiffness rings available (very soft, soft, medium, firm, very firm), accommodating subjects' weights from 41 to 113 kg. We are testing all five, each at three weights representative of the maximum, minimum, and mean values for the manufacturer's recommended range of weight values for that particular ring.

The Seattle is a pressurized pneumatic cylinder that suspends weight on pressurized air; it is is designed to accommodate persons weighing up to 136 kg. Because pressure is controlled by an air pump and allows for a continuous range of values, we assumed three different body weights (BW) over the range of values recommended by the manufacturer and set the air pressure equal to 0.5 BW psi and 0.5 BW±25 percent BW psi.

PROGRESS—Laboratory testing of the three pylons has been completed; data are currently being reduced, and will be processed in order to calculate the desired parameters for characterizing the three shock-absorbing systems.

FUTURE PLANS—After the static and dynamic properties of the pylons have been fully characterized, we plan to perform clinical testing with the devices. Persons with unilateral transtibial amputation will be recruited for gait analyses, and we plan to have them walk both with and without the pylons, while kinematic measurements and ground reaction forces are acquired. By comparing measurements from two conditions, we can determine whether or not the devices significantly affect the pattern of walking. Gait parameters that we plan to investigate include speed, cadence, vertical displacement of the trunk, step length, stride length, and pelvic obliquity. The subjects' gait data will also be compared with that of controls to determine whether the mechanisms enable them to walk more normally.

C. Lower Limb: Transfemoral

[20] DEVELOPMENTAL ENHANCEMENT AND APPLICATION OF THE VA-CYBERWARE PROSTHETICS-ORTHOTICS OPTICAL LASER DIGITIZER

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PURPOSE—The objectives of this project are to continue refinement and enhancement of the VA-Cyberware Prosthetics-Orthotics Optical Laser Digitizer and to conduct fundamental application studies with the optical digitizer to test and demonstrate its capabilities, effectiveness and efficiency in quantitatively characterizing the spatial geometry and surface topography of amputees' residual limbs and orthotics patients' limb segments.

METHODOLOGY—To achieve these objectives, the following research protocol was established:

1. Develop refined and enhanced design specifications for, and procure and test a new, second generation, prototype optical digitizer, correcting the deficits identified in the original prototype digitizer, and further improving and extending its capabilities and performance;
2. Optimize and enhance the digitizer control, data acquisition, processing, visualization, and analysis software modules developed for use with the original digitizer prototype, integrating them into a user-friendly, menu driven program for clinical prosthetics-orthotics use;
3. Develop improved lower limb prosthetics CAD system design templates based on optically digitized residual limb measurements;
4. Refine and optimize the control, tool path clearance, and the surface contour interpolation and smoothing software for the VA Prosthetics-Orthotics CAM milling machine to enable WYSIWYG prosthesis-orthosis design and manufacture from optical scan measurements; and
5. Develop CAD templates for design of ankle-foot orthoses (AFOs) and knee-ankle-foot orthoses (KAFOs) from optically digitized limb segment measurements.

PROGRESS—A new, second generation optical digitizer prototype, based on the design specifications developed in the project, correcting all the deficits identified in the original digitizer prototype, and further improving and enhancing its performance and capabilities, was constructed. Laboratory calibration and rigorous testing of the digitizer was begun. Work continued on porting and optimizing the software modules developed on an engineering workstation for digitizer control, measurement acquisition, processing, visualization, and analysis, to a PC platform for clinical prosthetics-orthotics deployment. Work on integrating and refining these modules into a single, composite, user-friendly, menu-driven program for use by prosthetics-orthotics clinicians was instituted. Automation and refinement of calibration and testing procedures to optimize the digitizer's spatial field of view, and correct acquired measurements for optical nonlinearities, thus increasing the digitizer's accuracy, continued. Enhancement and optimization of the control, tool path clearance, and the surface contour interpolation and smoothing software for the VA Prosthetics-Orthotics CAM milling machine was completed. Development and refinement of CAD system prosthesis and orthosis design templates based on optically digitized residual limb/limb segment measurements also continued.

FUTURE PLANS—Refinement and enhancement of the optical digitizer shall continue, based on feedback from advanced application studies. These studies shall include the compilation of a quantitative prosthetics and orthotics patient database of residual limb/limb segment geometries, measurements, and histories for use in developing improved prosthetic socket and orthosis designs; the compilation of a database of patient limb segment contours, areas, and volumes for correlation with, and quantitative assessment of, the efficacy of medical treatments and rehabilitation regimens; and the utilization of the digitizer as an educational tool for direct visualization of prosthetics-orthotics principles and analysis of clinical practices.

RECENT PUBLICATIONS FROM THIS RESEARCH

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The VA-cyberware lower limb prosthetics-orthotics optical laser digitizer. Houston VL, Mason CP, Beattie AC, et al. J Rehabil Res Dev 1995;32(1):68–84.

[21] TISSUE BIOMECHANICAL AND VASCULAR STUDIES FOR IMPROVED PROSTHETIC SOCKET DESIGN

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PURPOSE—The purpose of this project is to investigate residual limb tissue biomechanical and vascular characteristics and geometry, and quantify prosthetic loading so fundamental socket design principles and algorithms can be derived, that afford more intimately fitting, comfortable, and functional sockets for persons with lower limb amputation.

METHODOLOGY—To achieve this objective, the following research protocol has been delineated: for a ‘‘representative’’ sample of physiologically mature and prosthetically habituated persons with transtibial amputation:

1. Measure and digitize the subjects' residual limb spatial geometry and tissue morphology;
2. Measure the biomechanical characteristics of the subjects' bulk, soft, residual limb tissues, and derive 3-D, nonlinear, viscoelastic finite element (FE) models of their residual limbs;
3. Measure socket/residual limb interface stresses for the subjects during stance and gait;
4. Compute FE predicted residual limb tissue stress and strain distributions for the subjects in their sockets under simulated loads equivalent to those measured, comparing the resulting finite element analysis (FEA) predicted tissue displacements and FEA predicted tissue surface stress distributions with magnetic resonance (MR) measured displacements at key anatomical locations, together with corresponding measured socket interface stresses, for validation of the FE modeling and analysis procedures;
5. Map the subjects' principal residual and contralateral limb vasculature, and measure their respective vascular flow velocities and volumes, without their sockets, and with their sockets on under axially applied loads, using MR angiography and flow measurement techniques;
6. Measure the changes in the subjects' socket/residual limb interface stress distributions and tissue perfusion velocities and volumes produced by various prosthetic socket design geometries, and compare the results with corresponding FEA predicted residual limb stress and strain distributions;
7. Analyze the information and measurements compiled, and formulate socket design principles therefrom, as a function of tissue biomechanical

characteristics, vascular state, and applied prosthetic loads; and

8. Develop CAD system socket design algorithms implementing the formulated design principles, and clinically test and measure the degree of fit, comfort, and function provided by the resulting CAD designs.

PROGRESS—An electromechanical indentor with force/position feedback was constructed, and the biomechanical creep and stress relaxation responses of the residual limb tissues of 16 test subjects were measured, and subsequently mathematically modeled by viscoelastic exponential and steady state Ogden elastomeric material models. The residual limbs of three of these subjects one with ''representative'' soft durometer tissues, one with ''representative'' average durometer tissues, and one with ''representative'' firm durometer tissues were digitized optically and with a high resolution MR scanner. FE models of these residual limbs were created from the data compiled. The subjects' well-fitting, habituated sockets were also electromechanically digitized. Static and dynamic socket/limb interface stresses were then measured with VA-Tekscan P-Scan transducers for these subjects in their original, well-fitting sockets, and in two experimental sockets with popliteal depression and posterior brim design variations, but otherwise identical in design to the original sockets. MR high resolution morphological scans, angiograms, and flow velocity and volume scans of the popliteal arteries of the subjects in the respective sockets with 32 KG static, axial loads applied were acquired. Corresponding FE simulations of the socket application and loading tests were performed, and the resulting FEA predicted residual limb tissue displacements at five key locations were compared with actual MR measured displacements. Similarly, FEA predicted surface stresses were compared to actual P-Scan measured socket/limb interface stresses. The reasonably close approximation of the measured displacements and stresses by the FEA results, established the FE modeling techniques employed as useful and effective prosthetics design and analysis tools.

FUTURE PLANS—The project tissue biomechanical and vascular studies shall continue with a range of ''representative'' subjects. The biomechanical studies shall be expanded to include measurement and modeling of tissue anisotropic characteristics. Models of the principal vasculature shall be incorporated in the FE models developed to allow prediction of the effects of variations in socket design geometry and prosthetic loading upon residual limb circulation. With compilation of measurements for a statistically significant sample of subjects, the data acquired shall be analyzed to formulate quantitative socket design principles and development of CASD algorithms allowing determination of ''how much'' and ''where'' residual limb geometries need to be modified to achieve well-fitting, comfortable, and functional sockets.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Tissue finite element studies for improved prosthetic socket design. Houston VL, Luo G, Mason CP, et al. Proceedings of the Second Annual MARC Conference on Finite Element Methods in Bioengineering; 1997, Minneapolis, MN. MARC Analysis Research, 1997, 2-18.

[22] DEVELOPMENT OF A BIOMECHANICAL MODEL OF THE INTERFACE BETWEEN THE STUMP AND THE PROSTHESIS FOR TRANSFEMORAL AMPUTEES

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PURPOSE—A major limitation of present CAD/CAM systems, and indeed in clinical practice, is that no account is taken of the tissue properties of the residual limb or the actual loads and pressures transferred through it. The aim of this investigation is to generate a three dimensional (3-D) finite element (FE) model of the residual limb capable of predicting the load distribution at the patient/prosthesis interface. The introduction of FE analysis to CAD/CAM system can provide quantitative feedback to the prosthetist recommending rectification in the CAD software.

METHODOLOGY—The geometry of the residual limb FE model was obtained using magnetic resonance imaging (MRI) techniques. The subject was imaged wearing the quadrilateral and ischial containment type sockets. Images of the residual limb without socket were also captured. Prior to construction of the FE model, the transverse MRI images were processed digitally in order to extract tissue boundaries. The images were smoothed using a median filter, and boundaries were extracted using mathematical morphology based on shape analysis and description. The processed images were then reconstructed in 3-D by stacking the transverse images together.

The material properties of the soft tissue were estimated based on a mechanical indentation test. Load actions at the hip joint on the amputated side were introduced to the FE model. These kinetic data were collected suing a VICON motion analysis system and Kistler force platforms.

The FE model was validated by comparing the predicted interface pressure with measured pressures. A total of 36 sites on the socket walls were measured using a transducer incorporating a strain-gauged load cell.

PROGRESS—Other means of obtaining the geometry of the residual limb for FE modelling are being investigated. This includes the use of ultrasound imaging and anthropometric scaling techniques.

RESULTS—High pressures at the proximal brim of the quadrilateral socket and a more evenly distributed pressures in the ischial containment socket were predicted. Similarities were observed with the measured pressures. However, most predicted pressures were lower than measured pressures.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Stump/socket interface pressure as an aid to socket design in prostheses for transfemoral amputees: a preliminary study. Lee VSP, Spence WD, Solomonidis SE. Eng Med Proc Instn Mech Engrs 1997;211(Part H)167–80.

Two dimensional finite element model of a transverse section of the trans-femoral amputee's stump. Lee VSP, Solomonidis SE, Spence WD. Proceedings of the 3rd International Symposium on Computer Methods in Biomechanics and Biomedical Engineering; 1997 May 7-10; Barcelona, Spain.

[23] HOW PROSTHETIC KNEE CENTER POSITION AFFECTS TOE CLEARANCE AND THE HIP-TOE DISTANCE

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PURPOSE—We have previously shown that 4-bar linkage knees are able to provide more toe clearance than single-axis knees during the swing phase of prosthetic walking. These results led us to consider how the position of the knee's center of rotation (CoR) affects the amount of toe clearance, and the hip-toe distance, during prosthetic swing. Four-bar knees are polycentric mechanisms: the position of the knee's CoR varies with the knee flexion angle. In all of the 4-bar knees that we investigated, the instant CoR moves anteriorly during the first 10–20° of knee flexion, and with additional knee flexion it moves posteriorly. We believe that this movement of the instant CoR is how 4-bar knees are able to provide more swing-phase toe clearance than a single-axis knee. Therefore, we performed computer simulations to determine how changing the anterior-posterior position of a single-axis knee center would affect toe clearance. We also investigated how different bench-top alignments in a transfemoral prosthesis can affect the hip-toe distance and toe-clearance.

METHODOLOGY—The kinematics of a transfemoral prosthesis having a single-axis knee were simulated with a computer. The computer program was originally developed for evaluating the kinematics of 4-bar linkage knees, but it was modified to permit investigation of the changes in toe clearance and the hip-toe distance as the anterior-posterior position of a single-axis knee was varied. Simulations were performed using this computer model having its axis (CoR) aligned posteriorly, and then anteriorly, with respect to its typical position in the German alignment recommended by Otto Bock. The computer model also allowed us to compare differences between the toe clearances and hip-toe distances produced by two different methods of aligning transfemoral prostheses: the German and the TKA (trochanter-knee-ankle) alignments.

RESULTS—We found that the anterior positioning of the single-axis knee decreased the hip-toe distance to a greater extent than when the knee was in the German alignment position, whereas the posterior alignment increased the hip-toe distance. This resulted in a greater toe clearance for the anterior aligned knee center, and less toe clearance for the posterior positioning, when compared with the typical knee alignment.

These results help explain how 4-bar linkage knees are able to provide more toe clearance than a single-axis knee. Because 4-bar knees are polycentric joints, their knee centers move from a relatively posterior position at full extension, compared with the single-axis knee's CoR, to a relative anterior position during the first 10–20° of rotation. Doing so allows the 4-bar knees to increase the toe clearance by shortening the hip-toe distance more so than in the single-axis knee having a stationary CoR. This gives the 4-bar knees greater stance-phase stability through posterior positioning of the knee center, and greater swing-phase toe clearance because of the anterior movement of the CoR as the knee flexes.

We also used the computer model of the single-axis knee to compare the amount of toe clearance obtained with the German alignment and the TKA alignment, finding that the German places the single-axis knee slightly more anterior in the prosthesis than the TKA, which increases toe clearance.

RECENT PUBLICATIONS FROM THIS RESEARCH

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An investigation of 4-bar linkage knees as an aid to floor clearance during swing. Gard SA, Childress DS, Uellendahl JE. Proceedings of the 8th World Congress of the International Society of Prosthetics and Orthotists; 1995, Melbourne, Australia.

[24] A KNEE JOINT FOR USE IN A PEDIATRIC SWIMMING PROSTHESIS FOR PERSONS WITH TRANSFEMORAL AMPUTATION

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PURPOSE—There are currently few alternatives for swimming prostheses for the person with transfemoral amputation, since most conventional prostheses will not stand up to repeated usage in water and related such elements as sand, chlorine, and salt that accompany participation in such activities. The majority of swimming prostheses are rigid units with no knee flexion capability. Those that do offer knee flexion require complex, expensive, and time-consuming methods of manufacture. The focus of this project is to design and develop a simple, easily manufactured knee joint for use in a pediatric swimming prosthesis. The device will have the capability to lock during gait but will also provide knee flexion capability to allow the child to sit or play at floor level.

PROGRESS—Initially, work has focused on outlining the design requirements for the knee joint. Design loads have been investigated based on anthropometric data for the heights and weights of the children in the target population, as well as their expected level of activity. Detailed investigations of the environments in which the knee joint will be required to operate have been undertaken to identify the conditions which the materials and construction must withstand without functional degradation. Concurrently, studies into appropriate chemically resistive polymer materials and low cost manufacturing processes have begun in anticipation of the detailed design phase.

FUTURE PLANS—Upon selection of the materials and manufacturing process, the detailed design phase will begin to develop the joint unit based on the identified criteria. Subsequently, a prototype knee joint will be manufactured for bench testing, as well as for functional testing with an appropriate subject. Outcomes of bench tests, functional tests, and user feedback will identify appropriate design modifications required to maximize the utility of the swimming knee.

[25] THREE-DIMENSIONAL MODELLING OF THE TRANSFEMORAL RESIDUAL LIMB USING ULTRASOUND

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Sponsor: *None listed*

PURPOSE—Imaging methods that provide both the external and internal geometry of the residual limb would enhance CAD/CAM socket design and biomechanical modeling of the limb. Magnetic Resonance Imaging (MRI) and X-Ray Computed Tomography (CT) may be used for this purpose, but have several disadvantages. Other researchers have demonstrated the use of ultrasound for obtaining the geometry of the transtibial residual limb. The overall objective of this project is to construct a 3-D model of the residual limb of persons with transfemoral amputation using ultrasound B-scans. The initial aim is to define skin and bone in transverse images of the residual limb. The limb will be scanned while fitted with a prosthetic socket.

METHODOLOGY—Ultrasound B-scans of the residual limb are taken while the limb is immersed in a waterbath to which the ultrasound transducer is attached. The transducer is rotated in a horizontal plane around the residual limb and B-scans are taken at regular intervals. Image processing techniques are used to reconstruct transverse images of the limb and to extract the skin and bone boundaries from them. The transducer is translated vertically with respect to the limb in order to obtain sets of B-scans along its length, for 3-D reconstruction using standard software.

PROGRESS—Preliminary ultrasound scans of a leg of pork have been taken in the manner described above, and transverse images have been reconstructed. The transverse images show the boundaries of skin and bone, and work is in progress on optimizing the reconstruction process to reduce the blurring effects of subject movement during scanning. A scanning set-up has been designed and built for scanning the unloaded transfemoral residual limb.

FUTURE PLANS—The geometrical information obtained using ultrasound will be compared to that obtained using MRI. The effect of different socket types on the geometry of the residual limb will be studied. An investigation into the geometrical changes of the limb in response to loading is being considered.

C. Lower Limb: Transtibial

[26] FINITE ELEMENT AND GAIT ANALYSIS: TOOLS FOR PROSTHESIS DESIGN

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PURPOSE—The purpose of this project is the development of a new Computer Aided Design (CAD) tool based on finite element (FE) analysis of lower limb prosthetic sockets and clinical gait analysis data. The goal is to quantify aspects of socket fit such as load support, limb stability, and socket suspension, and subsequently generate a socket shape which optimizes each of these characteristics for a given limb shape.

METHODOLOGY—FE models of successfully fitted transtibial sockets and limb systems will be created in order to determine which quantitative parameters are representative of adequate load support, stability, and suspension. By analyzing a large database of socket shapes, we will determine acceptable ranges of values for each of these parameters. After determination of the parameter ranges, an experimental evaluation of sockets designed according to these principles will be used to determine the validity of the parameters identified in the previous phase. This will result in a set of target values for design parameters. Subsequent to experimental verification, the newly determined design guidelines will be used as a criteria for an automated optimized shape generation procedure.

Two hundred digitized residual limbs and sockets from successful CAD/CAM fittings will be made into FE models and analyzed under a typical gait loading pattern. Many different quantitative values from the results will be investigated in order to assess which are similar across all of these successful sockets, and which are representative of the characteristics of support, stability, and suspension. Some potential parameters include interface stress, magnitude of socket rotations relative to the limb, and axial translation distance. The results of these models will form a database from which acceptable ranges for each of these parameters will be determined. Subsequent to parameter identification, experimental evaluation of the effect of design parameter variation will be carried out. Three persons with transtibial amputation will be fit with sockets designed for varying levels of stability, support, and suspension, by adjusting the values of the design parameter representative of each characteristic. The quality of these sockets will be evaluated by the subjects themselves and by experienced prosthetists, to determine whether the parameter variation improved or worsened the socket with respect to support, stability, or suspension. This short-term evaluation will determine the validity of the parameters chosen. After appropriate ranges of values for each of the relevant parameters are established and verified, design optimization techniques will be applied to allow computer generation of shapes satisfying each design criterion. Various optimization methods will be evaluated. The method that provides the quickest convergence properties will be used for the final socket shape generation procedure.

PROGRESS—Currently we are collecting the limb shapes and socket files and converting these files to meshes for analysis. Software has been generated to completely automate this process. The model design algorithm appears capable of generating acceptable models across the database of limbs and sockets. The computer analysis of these models is currently under way. Concurrent with these analyses, software is being developed to facilitate the presentation and collection of the relevant data from the analysis results.

FUTURE PLANS—What comes next depends upon the outcome of the work. If the procedure makes good sockets, we will implement it in CAD/CAM trials.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[27] CLINICAL TESTING OF THE ENHANCED VA-CYBERWARE BK PROSTHETICS OPTICAL DIGITIZER

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PURPOSE—The objectives of this project are to update the design of and the software for the VA-Cyberware BK Prosthetics Optical Laser Digitizer and to test the digitizer clinically to establish the level of temporal efficiency, repeatability, and consistency it affords in characterization and measurement of spatial geometry and surface topography of the residual limb of persons with transtibial amputation, in comparison to current CAD plaster wrap cast/electromechanical digitization techniques.

METHODOLOGY—To achieve these objectives, the following research protocol has been established:

1. To update the design of the software for the optical digitizer;
2. To procure, calibrate, and laboratory test five enhanced optical digitizer prototypes;
3. To deploy the digitizer prototypes at five VA PSAS Prosthetics CAD/CAM Centers, and train their respective clinical prosthetics staffs in their function and use;
4. To conduct a clinical field trial with the optical digitizer at the five VA Prosthetics CAD/CAM centers, to establish the level of training and technical expertise required to operate the digitizer; the degree of repeatability, consistency, and temporal efficiency afforded by the optical digitizer in capturing and measuring BK amputee residual limb spatial geometry and surface topography, especially in comparison with current CAD plaster wrap cast/electromechanical digitization techniques; and to establish the level of durability, maintainability, and reliability of the digitizer in a clinical setting; and (5) To compile, analyze, and document the results of the clinical tests, to identify any additional design refinements and/or clinical enhancements required in either the digitizer hardware or software before it is released to commercial production and general clinical deployment.

PROGRESS—The design of the optical digitizer was upgraded to incorporate more advanced optoelectromechanical components, and to make it more robust, durable, and to require less maintenance in a clinical setting. An initial enhanced prototype was procured for development of testing and calibration devices and procedures, and five clinical prototype units ordered. Work was begun on porting digitizer control, data acquisition, processing, measurement, analysis, and automated landmark detection, identification, and registration software for use with the new, enhanced digitizer prototype. Development of installation, training, and user manuals for the digitizer was also begun in preparation for the clinical trials.

FUTURE PLANS—Clinical field testing of the digitizer shall commence following procurement and laboratory testing and calibration of the five prototype units. The test data compiled in the field trials of the digitizer shall be analyzed and recommendations made for incorporation of any enhancements and design refinements found to be appropriate. Further application studies with the digitizer shall include the compilation of a quantitative prosthetics and orthotics patient database of residual limb/limb segment geometries, measurements, and histories for use in developing improved prosthetic socket and orthosis designs; the compilation of a database of patient limb segment contours, areas, and volumes for correlation with, and quantitative assessment of, the efficacy of medical treatments and rehabilitation regimens; and the utilization of the digitizer as an educational tool for direct visualization of prosthetics-orthotics principles and analysis of clinical practices.

[28] INTERFACE MECHANICS IN LOWER-LIMB PROSTHETICS: EXPERIMENTAL MEASUREMENTS AND FINITE ELEMENT MODELING

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PURPOSE—The purpose of this research is to use both experimental and analytical techniques to investigate residual limb characteristics and prosthesis design features that strongly influence the distribution of mechanical stress at the residual limb-prosthetic socket interface. A quantitative understanding of how different features influence interface pressures and shear stresses will provide useful tools for enhancing prosthetic design and fitting.

METHODOLOGY—Persons with unilateral transtibial amputations using total contact patellar-tendon-bearing prostheses are participating in this study. Using custom-designed instrumentation, pressures and shear stresses are measured at 13 socket sites simultaneously, and forces and moments in the shank are also monitored. Residual limb shape before and after the session is measured using a custom-designed silhouette scanner, a device that images the residual limb in less than 1 s and has a resolution of approximately 0.5 mm. To date, studies investigating effects of changes in alignment, changes in walking speed, changes in prosthetic componentry, and changes in time of day have been conducted. In addition to the experimental measurements, analytical finite element (FE) models are also being pursued so as to allow sensitivity analysis evaluation of features that cannot be well assessed experimentally (e.g., interface materials). Custom-written code is being used in combination with a commercial software package.

PROGRESS—To date, 29 data collection sessions have been completed and analysis of the experimental data is near completion. The FE model allows for nonlinear tissue properties and frictional contact at the residual limb-prosthetic socket interface.

RESULTS—Results from the experimental studies on the subjects have demonstrated some interesting trends: interface shear stresses in the proximal socket region tend to be directed proximally toward the brim rather than distally toward the foot; anterior-distal shear stresses tend to be of the highest magnitude of all measurement sites, and shear stresses tend to be directed towards the apex of the socket at that location if the subject does not distal end-bear; changes in alignment, componentry, and walking speed tend to have less of an effect changing interface stress magnitudes, than do session-to-session differences. In the FE modeling effort, an automated hexahedral mesh generator was developed, an important tool to allow effective modeling of nonlinear materials and contact surfaces that undergo large displacements.

FUTURE PLANS/IMPLICATIONS—A next step will be to evaluate the nonlinear analytical models to determine if the results match experimental findings. We are particularly interested in investigating effects of changes in residual limb shape on interface stress distributions, using the thermal expansion capabilities of the program to model residual limb shape changes.

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[29] POSTURAL ADJUSTMENTS DURING STANDING IN BELOW-KNEE AMPUTEES

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PURPOSE—Postural control of persons with a limb amputation presents a very interesting model for the investigation of a central adaptation to the transformation of peripheral motor and sensory conditions. Both components of postural adjustments, compensatory and anticipatory are expected to be changed in such persons because of both mechanical and secondary, neurological reasons. We studied the role of adaptive changes within the central nervous system in anticipatory postural adjustments seen in persons with unilateral transtibial amputation.

METHODOLOGY—Six subjects with left transtibial amputation (TTA) and six age- and gender-matched controls participated in the study. The subjects stood on a biomechanical platform and performed fast bilateral shoulder flexions and extensions, load release (2 lb) from a rigid bar held in extended arms, or load catching (2 lb) on the bar described above. The EMG activity of 10 postural leg and trunk muscles from both the amputated and intact sides of the body and from anterior and posterior deltoid muscles; ground reaction forces and moments of forces; angles of the ankle, knee, and hip joints; and acceleration of the arms or bar were recorded. Integral EMG measures, horizontal displacements of the center of pressure (CP), and leg angle displacements were used to characterize the anticipatory adjustments.

RESULTS—Typically, changes in the activity of the postural muscles were observed from prior to the first visible changes in the activity of the prime mover to load release, or to load impact, in both groups of subjects. Generally, an increase in the activity was seen in muscles whose action opposed the expected postural perturbation. However, a clear asymmetry was seen in the patterns of EMG activity and mechanical variables recorded in TTA subjects from the intact and amputated sides of the body that was not seen in the control subjects. Anticipatory activity was seen in left and right erector spinae muscles. However, an anticipatory increase in the background activity of biceps femoris was seen only on the intact side, which stimulated an anticipatory extension of the right knee only. The subsequent changes in biomechanics of the body led to a rotation torque in the transverse plane at the level of the pelvis, exemplified by the anticipatory lateral displacement of CP and the horizontal component of ground reaction force. There are also compensatory reactions to balance perturbations induced by the movement 70–80 msec after movement initiation.

The results show that changes in postural adjustment of TTA exist not only in compensatory corrections, but also in anticipatory adjustments and may be considered adaptive in reacquiring balance skills after amputation. Rehabilitation approaches would benefit from understanding and taking advantage of the adaptive changes within the central nervous system.

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II. Biomechanics

A. Bone and Joint Studies

[30] EFFECT OF THE BANKART LESION ON ANTERIOR JOINT STABILITY WITH SIMULATED GLENOHUMERAL MUSCLE FORCES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A880-RA)*

PURPOSE—The objective of this project is to biomechanically assess the contribution of two common shoulder injuries to glenohumeral instability: tear of the origin of the inferior glenohumeral ligament (the Bankart lesion) and joint effusion.

METHODOLOGY—To study the effect of the Bankart lesion and joint effusion on glenohumeral joint kinematics and kinetics requires a building of a custom shoulder loading apparatus that utilizes a six axes load cell, six degrees of freedom (DOF) electromagnetic tracking device, four differential variable reluctance transducers (DVRT), and a video digitizing system (VDS). Using this device, we will biomechanically investigate both the passive and active stabilizing structures of the glenohumeral joint.

PROGRESS—The custom glenohumeral joint tensile testing jig, shoulder translation testing jig, and a shoulder loading apparatus equipped with six axes load cell and magnetic tracking devices have been completed. The translation testing jig permits the testing of passive restraints of the glenohumeral joint. The custom loading device permits the application of each individual muscle forces in the shoulder while permitting simultaneous measurement of the glenohumeral joint compression force and kinematics. The joint compression force is measured with the six axes load cell and the glenohumeral joint kinematics is measured with the magnetic tracking device. In addition, the inferior glenohumeral ligament (IGHL) origin as well as the permanent stretching of the IGHL tissue substance has also been determined.

PRELIMINARY RESULTS—Biomechanical results of the IGHL tensile tests showed that eight (66 percent) of the b-l-l-b complexes failed at the glenoid insertion site (representing the Bankart lesion), two (17 percent) at the humeral insertion site, and two (17 percent) at the anterior band midsubstance. Yield load was 579±63 N (mean±SEM) and the ultimate load was 676±59 N. Yield stress was 9.4±2.3 MPa and the ultimate stress was 10.8±2.3 MPa. Yield deformation was 11.9±0.5 mm and the ultimate deformation was 14.2±0.4 mm. On average, the permanent deformation, the difference between yield and ultimate deformation, was only 2.3 mm. Strain at failure was largest at the glenoid insertion of the anterior band on the labrum (17.1±1.7 percent). The humeral insertion strain (17.5±2.4 percent) was greater than at the anterior band midsubstance (8.9±1.0 percent). Interestingly, there was also considerable strain in the anterior band insertion on the glenoid proximal to the labrum (12.1±1.8 percent). Histology results showed that the anterior band of the IGHL has two attachments at the glenoid insertion site: the labrum and the anterior glenoid neck. The labral attachment is comprised of poorly organized collagen fibers that have direct insertion into the fibrocartilagenous labrum. The glenoid attachment is composed of dense collagen fibers that extend proximal to the articular margin of the glenoid and have an indirect insertion into the bone at a distance of more than 10 mm. There is only slight permanent stretching of the anterior band with the initial traumatic dislocation. This experimental model demonstrates that most of the strain occurs at the insertion sites, with failure occurring most often at the glenoid insertion. Current operative techniques for the treatment of anterior glenohumeral instability that repair only the labral attachment of the anterior band of the IGHL are insufficient. With surgical repair of the of the Bankart lesion, the glenoid attachment should be incorporated into the labral attachment repair and only slight shortening of the anterior band (about 6 percent) is necessary to restore the joint anatomy after initial glenohumeral dislocation.

FUTURE PLANS—Fresh-frozen full upper limb specimens will be mounted by rigidly attaching the scapula on the shoulder testing apparatus. The muscles simulated are those active in abduction of the joint: deltoid (middle and upper portions), supraspinatus, subscapularis, and the infraspinatus/teres minor. The scapula will be positioned in 30° of abduction and muscle force will be applied to the tendons of the simulated muscles until the shoulder joint reaches 90° of abduction. The force in the infraspinatus/teres minor muscles will then be increased for maximum external rotation. Glenohumeral joint motion will be measured with a six DOF magnetic tracking device. Three DVRT's and continuous VDS will be used to determine *in-situ* strain in the IGHL. The IGHL will then be tested in tension to determine the *in-situ* stress. For the measurement of the resultant glenohumeral joint compression force, a six axes load cell will be used. A Bankart lesion will then be surgically created and the test repeated again. At the completion of joint motion, each glenohumeral joint will be dissected and the center of curvatures for the humeral head and the glenoid will be determined.

[31] BIOMECHANICS OF THE PATELLOFEMORAL JOINT AND PERIPATELLAR RETINACULUM

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A881-RA)*

PURPOSE—The purpose of this study is to quantify the structural and mechanical properties as well as the *in-situ* stress and forces in the peripatellar retinaculum. This study is designed to quantitatively assess the functional role of the peripatellar retinaculum, in addition to determining the effects of lateral patellar retinaculum release, tibial rotation, and complete transverse patellar fracture (defect).

METHODOLOGY—Fresh frozen human cadaver knees will be used with an Instron machine and a custom patellofemoral joint loading jig that permits the measurement of strain in the peripatellar retinaculum while controlling the knee flexion angle, degree of tibial rotation, and tension in the quadriceps muscles (rectus femoris/vastus intermedius as well as vastus medialis and vastus lateralis). The patellofemoral contact pressures will be measured using Fuji pressure-sensitive film. The mean strain in the peripatellar retinaculum will be measured using six differential variable reluctance transducers (DVRT), and the surface strain will be measured using the video digitizing system (VDS). To determine the *in-situ* stress and forces in the peripatellar retinaculum, the *in-situ* strain is first measured in intact knees. The peripatellar retinaculum is then isolated for tensile testing to determine both the structural and mechanical properties. The results will then be correlated to compute *in-situ* stress and forces in peripatellar retinaculum.

PROGRESS—The patellofemoral joint loading jig has been built. This jig allows 5 degrees of freedom (DOF) at the femur and 3 DOF at the tibia. Muscle loading can be accomplished through stainless steel clamps, an adjustable pulley system, and lead weights. This custom jig permits independent application of all knee extensor muscle (rectus femoris/vastus intermedius, vastus lateralis, vastus medius, iliotibial band) forces in its anatomic/physiologic orientation at any knee flexion angle. This jig also permits simultaneous measurement of the patellofemoral joint contact pressures and kinematics using Fuji pressure sensitive film and a 3-D magnetic tracking device, respectively. We have also determined the anatomic/physiologic loading conditions for the *in-vitro* testing of the patellofemoral joint. This loading configuration was used for the quantification of the changes in the patellofemoral contact pressures as well as the *in-situ* strain in the peripatellar retinaculum resulting from tibial rotation. The tibial rotation had a significant effect on the patellofemoral contact pressures and the *in-situ* strain in the retinaculum. The increase in the patellofemoral contact pressures due to tibial rotation was observed for both internal and external rotation of the tibia with the effects being greater for the external tibial rotation. In addition, data show the greatest increases in the patellofemoral contact pressures occur at full extension. The results from this study suggest an inverse relationship between increasing knee flexion angles and the percentage change in mean patellofemoral contact pressures with rotation, especially external rotation. The results also suggests that there is a decrease in the strain of the contralateral side of the retinaculum with respect to the direction of the tibial rotation.

FUTURE PLANS—We plan to determine the tissue strain and stress in the peripatellar retinaculum as well as the patellofemoral contact pressures for lateral retinacular release and transverse patellar fracture (defect). Peripatellar retinaculum is an essential, complex, anisotropic, multilayered tissue for patellar stabilization. The residual strain and stress in these tissues, however, still needs to be quantified and further biomechanical and histological studies are necessary to accurately predict the *in-situ* stress in this complex tissue structure.

[32] FRACTURE OCCURRENCE AND HEALING IN SPINAL CORD INJURED PATIENTS

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No report was received for this issue.

[33] MECHANICAL LOADING EFFECTS ON CARTILAGE REPAIR AND REGENERATION

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PURPOSE—This study addresses mechanisms by which mechanical loads influence rehabilitation of joint function through tissue repair and regeneration. The goal is to develop information applicable to interventional techniques for restoration of joint function in arthritis. The experimental aims seek to establish the effects of varying levels and frequencies of hydrostatic pressure on articular chondrocyte matrix synthesis, proteoglycan gene expression, and cartilage type-specific collagen synthesis. The hypothesis addressed in this study is that cartilage repair and regeneration can occur given proper mechanical and biological stimulation. The process of understanding the mechanical loading conditions that augment cartilage matrix synthesis will permit development of a functional implantable cartilage-like tissue-substitute for arthritic joints.

METHODOLOGY—The experiments involve the isolation and culture of normal bovine articular chondrocytes in high density primary monolayer cultures for exposure to mechanical loading regimens. The cells are collected by sterile dissection and enzymatic dissociation of cartilage from radiocarpal joints of adult bovines (age 5–7 yrs). The mechanical loading regimens include application of intermittent hydrostatic pressure at levels of 5, 10, 15, and 20 MPa at frequencies of 0.1, 1, 5, and 10 Hz. The mechanical loading is carried out by placing culture dishes containing the cells in high density monolayers into medium-filled bags contained in a high pressure vessel. After loading, the cell culture medium is collected for analysis of protein, proteoglycans, and glycosaminoglycan content. The cell monolayer is then extracted, using a modification of the guanidinium isothiocyanate methodology for recovery of total cellular nucleic acid. Gene expression is analyzed by semi-quantitative RT-PCR methodology, using cDNA and primer pairs designed for amplification of cartilage-specific markers. Quantification of mRNA signal levels is based on detection of ^{32}P radioactivity. Replicate samples are tested for statistically significant differences using analysis of variance with multiple comparison testing by the general linear method applying Tukey's correction.

PROGRESS—The initial experiments concentrated on the cartilage type-specific collagen mRNA level, since collagen provides the framework for the extracellular matrix. Progress has involved optimization of the PCR conditions for analysis of type II and type I collagen mRNA levels relative to a reference signal for beta-actin. Use of a single reaction mixture for quantification of each collagen mRNA signal proved unsuccessful. Competition between primer species for type II collagen and beta-actin necessitated individual reaction mixes and required optimization of the individual primer sets as independent series. This work has progressed well. Five sets of chondrocyte cultures have been exposed to intermittent hydrostatic pressure at 10 MPa with a frequency of 1 Hz for periods of 2, 4, 8, 12, and 24 hrs and have yielded a profile for collagen expression.

RESULTS—The data obtained represented articular chondrocytes placed in monolayer culture in the presence of 10 percent serum and then mechanically loaded in serum-free medium following a 24-hr period of serum-washout. Under these conditions, type II collagen expression was relatively abundant and the levels of mRNA did not vary significantly during the periods tested. Detection of type I collagen expression required an increased number of cycles of PCR and the existence of type I collagen signal varied with cell preparation. Signal levels for beta-actin mRNA revealed that this marker of chondrocyte metabolism was also relatively abundant and that the levels of expression did not vary with exposure to intermittent hydrostatic pressure.

FUTURE PLANS—The experimental protocols will continue by examining effects of different levels of intermittent hydrostatic pressure on the cells. Quantification of the chondrocyte response will be expanded to include analysis of aggrecan core protein mRNA signal. In addition, effects of hydrostatic pressure on protein and glycosaminoglycan levels in the culture medium will be determined.

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[34] THE EFFECT OF HYDROSTATIC PRESSURE ON INTERVERTEBRAL DISC METABOLISM

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PURPOSE—The etiology of many causes of low back pain can be linked to disc degeneration, a condition that may be the first step in the development of osteoarthritis and stenosis in the lumbar spine. It is commonly held that the forces applied to the intervertebral disc play a major role in causing disc degeneration. However, the nature of the association between applied force and disc degeneration remains obscure. It has been suggested that in some cases the applied force generates a mechanical stress that acts in cyclic fatigue to damage the disc at a rate faster than the normal biologic repair mechanism. This is a popular and a convenient explanation, but fails to explain the underlying biologic processes and the fact that intervertebral disc degeneration can also result from insufficient loading such as that seen with prolonged space travel and bed rest.

This project tests the hypothesis that hydrostatic pressure directly affects the synthesis of collagen and aggrecan (the cartilage-specific proteoglycan) by intervertebral disc cells. The long-term objective is to determine how hydrostatic pressure is transduced into the biological response within the intervertebral disc cells. Specifically, the experiments described are designed to determine how hydrostatic pressure influences the mechanisms responsible for normal disc maintenance and to identify specific biomarkers that can be used to indicate deviations from normal values. Knowing which steps in disc cell metabolism are sensitive to hydrostatic pressure could become an important asset in understanding and preventing disc degeneration.

METHODOLOGY—We have been carrying out experiments using canine intervertebral disc cells cultured in alginate and subjected to 1 MPa pressure for 9 days. The culture system takes advantage of an alginate (a linear copolymer of D-mannuronic acid and L-guluronic acid) which polymerizes to form a gel in the presence of calcium ions. This system has been the choice of a number of investigators in the study of cartilage cell metabolism. In our experiments, the intervertebral disc cells are exposed to a specific value of hydrostatic pressure inside a pressure chamber. The cells are then recovered by dissolution of the alginate gel in calcium-free buffer containing the chelating agent, ethylenediamine tetracetate (EDTA). The biosynthesis of the extracellular matrix (ECM) components (the proteoglycans and collagen) are then measured.

PROGRESS—Using a specially designed pressure vessel, results show a differential response of nucleus and anulus cells to 1 MPa of pressure (0.1 MPa≈atmospheric pressure). Incorporation of [^{3}H]-proline and [^{35}S]-sulfate into collagen and aggrecan, respectively was stimulated in nucleus cells and inhibited in anulus cells compared to controls at 0.1 MPa.

FUTURE PLANS—We will continue these experiments at different values of hydrostatic pressure in the range of 0.1 MPa to 2.0 MPa (at least two values above and two below 1 MPa). We will also determine whether the biosynthetic response is a reflection of changes in mRNA levels for collagen types I and II and the aggrecan core protein using the RT-PCR methodology. Using the same culture system and the same biochemical and molecular methodologies, we will measure the biosynthetic response of intervertebral disc cells to hydrostatic pressure applied cyclically. To carry out these experiments, we have designed and built a cyclic pressure apparatus that has been tested and observed to be fully functional.

[35] BIOMECHANICS OF FOOT DEFORMITIES AND ALTERNATIVES FOR SURGICAL CORRECTION

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No report was received for this issue.

[36] DEVELOPMENT OF A SHOULDER AND ELBOW MUSCULOSKELETAL MODEL: CLINICAL AND ERGONOMIC APPLICATIONS

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PURPOSE—In the past years, a detailed musculoskeletal model of the shoulder has been developed, including the scapular and clavicular motion. The purpose of our research is to obtain a better knowledge of the biomechanics and control of the upper limbs, in order to improve the clinical diagnosis and treatment, and ergonomic prevention of disorders.

METHODOLOGY—We have extended the existing shoulder model with the flexion/extension joint and the pro/supination joint. The current model consists of 31 muscles and muscle parts, represented by 115 muscle lines of action, wrapped around muscle contours when applicable. In a separate morphological study, the sarcomere length of all shoulder and elbow muscles has been measured using laser diffraction. From these data, the optimum fiber length, pennation angle, and tendon length can be derived, and hence the force-length curve. Image processing techniques are being used to assess the muscle attachments *in vivo* from MRI and CT-scans.

Rozendaal has analyzed the role of geometrical factors (change of moment arms), intrinsic muscle properties (stiffness, viscosity), and reflexive muscle properties (length and velocity feedback, force feedback, including time-delays), on the impedance of a linearized musculoskeletal model. Using a robotic manipulator, model parameters for the intrinsic and reflexive properties are identified. Stroeve analyzed the properties of a combined feedforward and feedback (including time-delays) controller using a neural network.

In collaboration with the Department of Orthopaedics, University Hospital Leiden, a Flock-of-Birds system has been adapted and calibrated for motion recording of the shoulder (including scapula and clavicle) and elbow. Recorded motions can be directly used for a inverse dynamic analysis with the musculoskeletal model. A case study of a brachial plexus subject showed the potential of the model in predicting the mechanics of a disabled shoulder as well as the postoperative results.

In collaboration with the Department of Human Movement Sciences, Vrije Universiteit Amsterdam, recordings have been made of motions, external forces, EMG, and oxygen uptake during wheelchair propulsion. These data are used for assessment of mechanical load (e.g., of the glenohumeral joint) and of the power generation of the shoulder and elbow muscles in order to analyze the cause of energy losses resulting in a low mechanical efficiency.

PROGRESS—The shoulder model has been improved with better parameters (optimum muscle length), an elbow extension and control loops with muscle spindles and Golgi tendon organs. Rozendaal has shown that it was feasible to calculate the optimal feedback gains for individual muscles. By force perturbations of a robotic manipulator, the role of muscle spindles could be identified from the EMG. Simulations with neural networks showed that there was a high interaction between the feedforward (planning) and feedback control. The model has become reasonably user-friendly, and hence applicable in clinical and ergonomic settings.

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[37] DETECTION OF OSTEOPOROSIS THROUGH COMPUTERIZED ANALYSIS OF DISTAL RADIUS X-RAYS

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PURPOSE—The purpose of this study is to develop a sensitive and inexpensive method to diagnose osteoporosis based on computerized analysis of digitized x-rays. The quantification of structural rather than densitometric properties is the aim of this project. The distal radius has been chosen so far because it usually develops early osteoporotic signs and is an area prone to osteoporotic fractures. Further the cancellous bone content is high and radiographs of large numbers of patients are readily available.

METHODOLOGY—Distal radius x-rays are digitized using a high-resolution flat-bed scanner, interfaced to a personal computer. The images are converted to grey-level matrices and the grey-level variations are analyzed using frequency domain techniques, based on the Fast Fourier Transform (FFT). The magnitude peaks in the FFT are identified and their directions marked, permitting the determination of the preferred trabecular orientation in space. The magnitude of the peaks, expressed as a fraction of the total magnitude of the transform, permits a quantification of the trabeculae, expressed as a textural property of the image.

PROGRESS—The method is being considered for utilization in osteoporosis screening in places where densitometric methods are not available and where x-ray images have to be sent through telephone connections to be analyzed. Biomechanical studies are on their way to determine the ability of the method to predict the mechanical strength of bones.

RESULTS—Images have been analyzed in this way for a large number of clinical x-rays, and the results suggest that the ability to detect osteoporosis is similar to that of densitometric methods such as dual and single photon absorptiometry. The method is also able to detect the alterations that occur with fractures of the bones. The preliminary results with biomechanical testing show that the structural parameters have a significant correlation with the mechanical strength of the bones tested.

FUTURE PLANS—Comparative studies are being planned between spectral analysis and densitometric methods both on clinical and *in vitro* grounds. Other structural parameters, such as bone size and shape, are being considered, and combinations of these factors are being studied as bone strength predictors.

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[38] MICROCRACK MORPHOLOGY IN FATIGUED COMPACT BONE

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PURPOSE—Bone remodelling repairs fatigue-induced microdamage. Deficient repair results in fragility fractures, yet little is known of the behaviour of fatigue microcracks in bone. We have identified a series of fluorescent stains which are as effective as the standard method—basic fuchsin—in detecting microcracks but are also site-specific as they chelate Ca^{2+} ions lining the crack walls. We have shown that these chelating agents can be used sequentially to differentiate artefactual from test-induced damage and to label crack propagation. This study aims to refine this detection method, as binding strengths and levels of fluorescence vary among the agents, to use it to characterise microcrack initiation, propagation and coalescence in compact bone, and to relate microcrack generation to changes in the material properties of bone.

METHODOLOGY—Using microcracks generated during tensile testing, the minimum concentration of each chelating agent required to label the crack, as seen using epifluorescence, was established. Using these minimum concentrations, the growing microcracks were labelled at intervals with different agents to establish the optimal dye sequence.

PROGRESS—Coupons of bovine compact bone (35×25×2.5 mm) were prepared, a notch cut in one side and tested in tension to generate microcracks. Notches were cut obliquely with a diamond saw to avoid brittle fracture. The concentration of individual chelating agents applied (alizarin complexone, calcein, calcein blue, oxytetracycline, and xylenol orange) was varied from 0.001 to 1 percent to establish the minimum effective concentration necessary to bind to the walls and so label the crack, visualized using epifluorescence microscopy. Using these dosages, tensile tests were stopped at intervals and chelating agents applied to establish the optimal dye sequence for labelling segments of the propagating microcrack. Beams of compact bone (60×10×3 mm) were machined, polished, and fatigue tested in 3 or 4 point bending to 7,000 microstrain at 10 Hz. The optimal concentration and sequence of chelating agents were applied and growth of fatigue-induced microcracks monitored.

PRELIMINARY RESULTS—The optimal concentrations of each agent were: alizarin=0.015 percent, calcein=0.005 percent, calcein blue=0.015 percent, oxytetracycline=0.015 percent, xylenol orange=0.045 percent. The best single dye was found to be xylenol orange in a two-dye sequence (xylenol and calcein) and a three-dye sequence (alizarin, xylenol, and calcein). However, where a dye sequence was used, there was some evidence of the second dye displacing the first from the crack wall, suggesting either a mass effect or a greater affinity for exposed Ca^{2+} ions. Microcracks were easily generated in 3 point bending but were widely dispersed. Four point bending concentrated the stresses over a smaller area and the location and generation of microcracks was more easily predicted. Growth of fatigue-induced microcracks was labelled with a sequence of three chelating agents.

FUTURE PLANS—The stoichiometry of the chelating agents will be further refined by means of potentiometric titrations and X-ray crystallography. This method will then be applied to compact bone fatigue tested in four point bending and microcrack number and growth in length will be related to loss of bone stiffness and strength, for the first time. Microcrack morphology in serial sections will be recorded and, via a new computer package, a 3-D reconstruction made. This would be the first such attempt to show the passage of a crack through bone in 3-D. These data will be used to calibrate a finite element model of bone fatigue. Such a computer model, based on theoretical prediction and supported by experimentally derived material properties and morphological data would be a powerful tool in fracture prediction and orthopaedic prosthesis design.

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[39] QUANTITATIVE FUNCTIONAL ANATOMY OF THE UPPER EXTREMITY

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PURPOSE—Quantitative data on the morphology of shoulder and arm are needed as a basis for analysis of the load on the shoulder and arm, based on arm movement registration in wheelchair propulsion, activities of daily living, and vocational activities; analysis of the outcome of shoulder arthrodeses; and interpretation of *in-vivo* human palpation data.

METHODOLOGY—We are building a collection of musculoskeletal parameters of the shoulder and arm for biomechanical modelling of that region. Many of the clinical and ergonomical problems of the shoulder are the result of the complex co-ordination of the muscles involved in the control of shoulder movements and joint stabilization. This complexity of the human shoulder and arm cannot directly be studied, but needs the application of a 3-D biomechanical model. In addition, the 3-D nature of shoulder and arm motion and the covert motions of the scapula, require a highly sophisticated 3-D movement analysis.

PROGRESS—To date, morphological parameters have been collected on the shoulder mechanism as well as the arm. These data comprise 3-D insertion sites of muscles, the 3-D orientations of axes of rotation for elbow flexion/extension and pro/supination, and the rotation center of the glenohumeral joint. Also collected were data on muscle morphology such as muscle mass or physiological cross sectional area. These data have been implemented in a biomechanical model of the shoulder and arm. With the use of the model it is possible to calculate muscle forces, tensions in ligaments, and reaction forces in joints of the shoulder. Parallel to the model development, 3-D techniques for the measurement of kinematics have been developed. The program has been proven to be useful in the development of a sophisticated 3-D model of the shoulder mechanism that has been applied in the prediction of optimal fusion angles of shoulder arthrodeses after injury of the brachial plexus, in the analysis of the positioning of endoprostheses and operation techniques used, and in the quantification of mechanical load on the shoulder joint in manual wheelchair propulsion. Currently, the model is being applied in the analysis of the effect of glenohumeral joint stabilization requirements on the mechnical and physiological load of the manual wheelchair propulsion. Morphological data on these research projects are now available at http://www-mr.wbmt.tudelft.nl/shouder/dsg/dsg.info.html.

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B. Human Locomotion and Gait Training

[40] OBSTACLE AVOIDANCE TRAINING WITH COMPUTER-SIMULATED ENVIRONMENTS: A PILOT STUDY

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PURPOSE—Our work has focused on measuring characteristics of stepping-over responses (SORs) in overground walking and with computer-simulated objects on a treadmill. We have accomplished both of our stated objectives: to develop a method for displaying computer-generated obstacles so as to elicit stepping-over responses on a treadmill, and to demonstrate that these computer-generated SORs showed kinematic characteristics that were similar to overground SORs. In addition, we have conducted preliminary tests designed to show that our proposed training regimen (e.g., using computer-generated obstacles on a treadmill) is effective in improving overground SORs.

METHODOLOGY—We employed a head-mounted display to show a composite video image of the subjects with stationary virtual objects at their feet. They were asked to continually step over the obstacles with their left foot while on the treadmill.

PROGRESS—Five subjects have, so far, been enrolled in this part of the pilot project. All subjects are young, nonimpaired controls. Each person participated in two stepping sessions. In the first session, subjects were asked to walk down a walkway at a fixed speed and step over rectangular boxes of varying height and length. In the second experiment, subjects were asked to walk on a motorized treadmill while viewing their own legs and a computer-generated obstacle. The subjects were told to continually step over these simulated obstacles. Kinematics were measured using sagittal plane motion analysis. We measured hip, knee, and ankle angles, as well as foot height, step length, and step time when the leg was passing over the object.

The data collected show that we were successful in producing a method for eliciting SORs using computer-generated obstacles: they generate kinematic trajectories that are similar to overground SORs.

The second experiment involved three elderly subjects, one nonimpaired and two with stroke more than 3 years prior to testing. Both stroke subjects had regained fully independent ambulation but showed a noticeable lack in step height and stride length, which is exacerbated when asked to step over obstacles. Each person was initially tested on a 30.5 m course with nine foam obstacles 3 m apart. They walked this course as fast as possible, while carefully trying to avoid colliding with the objects. Then they practiced the proposed training regimen with simulated objects over a 3-day period, and were retested on the obstacle course.

RESULTS—Our work has led to the following conclusions:

1. Our most successful technique involves displaying a side-view of stepping on a treadmill while the viewer repeatedly negotiates computer-generated obstacles.
2. When stepping over obstacles during overground walking, young controls step over higher objects by increasing knee and hip flexion. This same strategy is employed when stepping over computer-generated obstacles displayed during treadmill walking.
3. When stepping over obstacles during overground walking, young controls step over longer objects by increasing stride length. This same strategy is employed when stepping over computer-generated obstacles displayed during treadmill walking.
4. In a small group of elderly subjects, the proposed training regimen showed a positive result in that subjects were better able to negotiate an overground obstacle course after 3 training sessions. A randomized, controlled study must be conducted to separate out the nonspecific effects.

[41] DESIGNING A BALLISTIC WALKING BIPED: ACTIVELY VARIABLE PASSIVE STIFFNESS

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PURPOSE—Previous research has shown that passive (or ballistic) walking is an energy-efficient and mechanically cheap way of walking. Therefore, ballistic walking would be suitable for applications in rehabilitation technology and autonomous robots. However, ballistic walking behavior is determined solely by intrinsic system parameters. Fixed system parameters imply lack of a possibility for adapting or changing the walking pattern, and of a possibility to intervene when disturbances must be controlled actively. This severely limits the practical use of ballistic walking. The purpose of this project is to develop methods of synthesis which make it possible to apply the ballistic walking principle in rehabilitation technology.

METHODOLOGY—Theory and practice support one another in order to form a firm basis of insight. Bifurcation theory gives insight in the influence of system parameters on the dynamics of the mechanical oscillating bipedal system, and stability can be quantified. This way, the open loop behavior of the system is optimized as much as possible. Further, feedback can be added to increase the orbital stability, or to adjust the mechanical oscillation. Therefore, adjustable passive components are needed, and these need to be controlled.

PROGRESS—A mathematical model of a simple bipedal walking movement is built gradually. Each effect of a model extension is to be studied in order to expose its effect on system behavior. Simultaneously, experiments are performed to verify theoretical validity. These actions build a toolbox that is to result in a method for synthesis of a desired ballistic walking movement.

PRELIMINARY RESULTS—A working prototype biped already has been constructed, and is capable of stiff-legged, stable, three dimensional walking on a horizontal surface. The ballistic walking motion is actuated solely by a periodic push-off, active for only one-forth of a step cycle. Also an actively variable passive stiffness joint has been developed. It facilitates the combinination of the advantages of passive motion with active control. It is believed that this joint can improve step width as well as robustness for external disturbances of the prototype.

[42] THE DEVELOPMENT OF A DIRECT ULTRASOUND RANGING SYSTEM FOR THE QUANTIFICATION OF AMBULATION

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PURPOSE—Full gait analysis capabilities for comprehensive studies of walking tend to be costly to develop and maintain. It was hoped that a simpler monitoring system could be developed which would capture some of the important information about gait performance but which would be relatively inexpensive to obtain, simple to use, and easy to maintain within small clinical offices. We developed the direct ultrasound ranging system (DURS) to meet these criteria.

METHODOLOGY—The DURS measures the instantaneous horizontal velocity of the approximate body center of mass (CM) during ambulation. The system accurately measures the periodic fluctuation in the forward velocity of the body trunk that results from the rising and falling of the CM during normal gait. DURS operates by emitting high intensity infrared pulses from a base unit at a rate of 22 pulses/s. A transponder worn by the subject is triggered by each infrared pulse to emit an ultrasound pulse. The time taken by the ultrasound pulse to travel from transponder to base unit is then measured. By calibrating for the speed of sound in air, this time difference can then be converted into a measure of the distance between the transponder and base unit. These distance samples are then stored and processed by a computer to yield the instantaneous velocity. Preliminary results suggest that the DURS can be utilized to accurately quantify certain parameters of ambulation. A patent application for our system has just been filed with the US Patent Office.

PROGRESS—The DURS is now in its second generation. The transmission and reception of both the infrared light and ultrasound signal have been improved to increase system range and robustness. This was accomplished by changing the configuration of the ultrasound and infrared emitters and receivers to enable the use of high-intensity infrared flooding. In addition, circuit changes and software upgrades were made. The DURS can now measure out to a distance of 14 m with standard deviations of less than 1 mm over the first 10 m, rising to 5 mm at 15 m.

FUTURE PLANS—The next stage of this project is clinical evaluation of six systems. In addition to gathering information about its use, this will also allow us to build up a database of pathological gait velocigrams. The DURS, when used in conjunction with a home video camera, offers an affordable and effective means of monitoring the recuperation of patients who have undergone corrective gait surgery, joint implant surgery, or who have been recently fitted with a lower-limb prosthesis. This device is portable, easy to setup and use, and provides results in real time, enabling changes to be tried and tested immediately.

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[43] CHARACTERISTICS OF AMPUTEE GAIT

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PURPOSE—Persons with unilateral transtibial or transfemoral amputations can often, with proper prosthetic fitting and rehabilitation, walk proficiently with little or no gross gait deviation. However, even adept prosthetic walkers are still known to ambulate with a slower speed and greater energy expenditure than their nonimpaired counterparts. While some deviation from normal walking could be inevitable, it may be possible to make aided ambulation on prostheses more efficient and comfortable by refining the prosthetic systems presently used. A better understanding of prosthetic ambulation will potentially lead to improved designs in prosthetic componentry.

The purpose of the present study was to enrich the understanding of prosthetic walking by gathering data concerning the gait of persons with transtibial and transfemoral amputation, noting patterns consistent among each group, and making comparisons to the gait data of velocity-matched controls. Focus in this study was placed on gait parameters in the coronal plane; these parameters have been largely ignored in the literature, yet have potential significance for persons with lower limb amputation in terms of balance, stability, and comfort. In order to assess whether alterations in the coronal-plane gait parameters are observable in prosthetic walking, several of these parameters were measured using gait analysis. Deviations from control walking were noted.

METHODOLOGY—Six persons with transtibial, and three with transfemoral, amputation participated in the study. Kinematic data were acquired using a CODA 3 Motion Measurement System as subjects walked along a 7-m walkway; ground reaction forces were measured simultaneously with two AMTI forceplates embedded in the walkway. Gait parameters investigated include velocity, cadence, step and stride length, stance time, trajectories and velocities of the pelvis, rotations of the pelvis in the coronal and transverse planes, the three components of the ground reaction force, and the transverse moment generated on the forceplate. Data from three male controls previously obtained in the laboratory were used as a reference in the present study.

RESULTS—The results of this study emphasize the importance of examining gait parameters with respect to the speed of ambulation when making comparisons between different walkers. Also highlighted is the marked deviation between subjects and controls with respect to the parameters of gait in the coronal plane. Specifically, the following observations were considered to be significant:

1. The subjects tended to increase their cadence and stride length to achieve greater walking velocities in a manner comparable to that of the controls.
2. The vertical trajectory of the pelvis measured from the subjects tended to be asymmetrical with respect to the stance limb, and their peak-to-peak values of vertical pelvic excursion tended to fall in and above the range of values established by the three controls.
3. The pelvic obliquity recorded from the subjects was characterized by distinct asymmetry of pattern and magnitude with respect to the weight-bearing limb. Higher levels of amputation were associated with lesser overall excursion of the pelvis in the coronal plane, in what is traditionally recognized as pelvic obliquity. This was especially evident during the period of weight-transfer to the prosthetic limb. There is a large excursion of the pelvis in the coronal plane, but this appears to be due to hip-hiking.
4. The pattern and amplitude of the medial-lateral ground reaction force measured from the two subject groups exhibited distinct deviations from the control group. Specifically, while the first peak in lateral reaction force was absent or decreased in magnitude in both subject groups, the medial component of force remained relatively unchanged.

FUTURE PLANS—This preliminary investigation characterized several aspects of prosthetic walking that have not previously been reported in the gait literature. This work suggests that there are several areas in which further study could lead to significant improvements in prosthetics practice. For example, the pattern of pelvic obliquity that was observed in the transtibial subject using a vertical shock pylon suggests further investigations are needed to determine the effect of vertical compliance mechanisms on the gait of persons with unilateral amputation. Also, deviant patterns of pelvic obliquity and an altered temporal relationship between the peaks of pelvic obliquity and the gait cycle observed in the transfemoral subject wearing a quadrilateral socket indicate that the effect of socket design on pelvic motion and other aspects of unilateral gait needs to be investigated.

We feel the characterization of prosthetic gait and the identification of factors inhibiting persons with amputation from walking more proficiently are important first steps toward the improvement of prosthetic design, fitting, and gait training.

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[44] THREE-DIMENSIONAL SENSITIVITY ANALYSIS OF SWING PHASE TOE CLEARANCE DURING GAIT

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PURPOSE—Foot clearance during the swing phase of walking is determined by the segment lengths and joint angles of the swing limb, stance limb, and pelvis. Foot clearance, also known as floor clearance, is defined as the perpendicular distance between the plane of the walking surface and a particular point on the swing-leg foot. Normal walking requires that the effective length of the swinging limb be shorter than the distance between the swing-leg hip and the ground in order to achieve foot clearance. Effective leg-shortening allows the swinging limb to be advanced in front of the body without contacting the ground and interrupting the gait cycle. We developed methods for determining the influence of the stance- and swing-limb joints on foot clearance and effective leg length during ambulation. The sensitivity analyses indicate how incremental changes in hip flexion/extension and ab/adduction, knee flexion/extension, and ankle dorsi/plantarflexion of both the swing and stance legs can affect the swing-leg toe clearance.

METHODOLOGY—Kinematic data describing the instantaneous positions of the joint centers of rotation (CoRs) from the swing leg, stance leg, and pelvis, and the position of the swing leg's great toe were acquired on two subjects. One of the subjects was a normal ambulator, and the other was a subject with a known leg length discrepancy resulting from congenital abnormalities.

PROGRESS—The original sensitivity analyses that we developed—the toe clearance sensitivity (TCS) analysis and the hip-toe distance sensitivity (HTDS) analysis—were two-dimensional and limited only to analysis of the swing leg joints. Recently, we have become quite interested in the contributions of the stance leg and pelvis in achieving and affecting swing leg toe clearance. Therefore, the original TCS and HTDS analyses have been expanded to include the effects of the pelvis and stance leg joints on the swing leg toe clearance, based upon the instantaneous positions of the joints'

CoRs, angular positions, and axes of rotation. These analyses indicate how rotations of the joints of the swing leg, stance leg, and pelvis affect swing leg toe clearance and hip-toe distance throughout the gait cycle.

RESULTS—We have yet to analyze all of our data, but preliminary data from normal walking shows that the stance leg ankle flexion/extension may have a much more significant effect on swing leg toe clearance than the literature has suggested. Other joint motions of the stance leg that appear to have a larger influence on swing leg toe clearance than we expected are knee flexion/extension, hip ab/adduction, and ankle inversion/eversion. Typically, toe clearance problems are attributed to the joints of the swinging limb during gait, but our results indicate that the stance leg and pelvis make significant contributions to foot clearance that cannot be ignored.

FUTURE PLANS—The TCS and HTDS analyses may prove to be beneficial for analyzing and diagnosing foot clearance problems in many different types of pathological gaits. Joints that have apparently normal kinematics during gait may still cause significant foot clearance problems if other joints in the kinematic chain (stance leg, pelvis, swing leg) have altered rotation patterns. The sensitivity analyses may also be useful for analyzing individual prosthetic components and assembled lower-limb prosthetic and orthotic appliances. We plan to work with orthopedic clinicians in developing practical applications and interpretation of the TCS and HTDS analyses.

[45] EXAMINATION OF ACTIVITIES AROUND STANDING

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PURPOSE—Standing upright is a mechanical feat, since the structure is comprised of a high center of mass with a small base of support; yet humans stand with minimal muscular effort. The question of how humans make the transition from standing to gait is addressed in this project. We have examined weight transfer from one limb to the other, walking in place, and gait initiation in forward, backward, and sideways directions. In addition to discovering insights into human locomotion, we hope to apply this knowledge to improve performance of persons who have difficulty initiating gait, such as those with bilateral lower limb amputation (TFA) and Parkinson's disease. TFAs have trouble starting gait, and many exhibit stop-and-go gait. Bilateral TFAs who wear ''stubbies'' usually display good standing abilities, but have a ''fall-stop'' type of gait. Each step is like an initial step. Training of persons who have walking difficulties is often based on concepts derived from steady-state walking. We believe the transitional stage of locomotion may reveal underlying mechanisms that make ambulation difficult for some people.

METHODOLOGY—We examined transitional periods of locomotion in six nonimpaired young adults who have no known balance or musculoskeletal disorders in weight transfer from one limb to the other, walking in place, and gait initiation in the forward, backward, and sideways directions. Pelvic motion and ground reaction forces and center of pressure were measured by the CODA-3 Motion Analysis System and two AMTI force plates. A minimum of three trials for each subject on each activity was recorded and analyzed.

PROGRESS—Data collection and analysis have been completed for all six subjects and mathematical models formulated. The first endeavor was a forward simulation of the period from initial limb toe-off to heel-contact. This simple two-dimensional model was composed of two links representing the trunk and leg segments in the sagittal plane. It also incorporates a rocker-based structure. This model, however, did not represent gait initiation well. Another model that incorporates an additional link to represent the pelvis has been proposed.

RESULTS—Similar results were found across the subjects as well as across the tasks, including vertical ground reaction forces, initial pelvic obliquity, and center of pressure excursions. Gait initiation studies in the literature have not yet addressed the role of the pelvis during the transition from steady-state standing to steady-state walking. We found that measurements of pelvic obliquity and vertical displacements of the markers placed on the right and left sides of the pelvis during the first step are markedly different from those found during the subsequent steps. The step-off side is elevated relative to the initial stance side. This rise is mainly due to hip hiking on the step-off side, probably in order to achieve surface clearance.

FUTURE PLANS—We hope to extend our experimental and modeling to better understand the dynamics of gait initiation.

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[46] A SIMPLE MODEL FOR STANDING AND BALANCE

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PURPOSE—Standing is a dynamic process involving balancing the body in a vertical position. In our efforts to understand balance involved in normal and pathological gait, we investigated the process of balance during standing. During standing, the center of mass (COM) of the body and the center of pressure (COP) move in what appears to be a random manner. Investigation of these motions may help in the understanding of standing balance. We have developed a new model describing human standing as a kind of tracking mechanism. This descriptive model will hopefully provide obvious indication of balance performance and suggest treatment for the balance-impaired, such as the elderly.

METHODOLOGY—A model describing human standing was developed by combining McRuer's control strategy for human tracking with Winter's model for standing based on the structure of an upright body. The resulting model indicates that during the process of standing, the velocity of the center of pressure (VCOP) is proportional to the acceleration of the center of mass (ACOM) with a time delay.

Three sets of experiments were used to support the validity of our model. Six nonimpaired controls between 20 and 40 years of age participated in one part of the research. A CODA-3 motion analysis system and two AMTI force plates were used to collect 30 s of position and force plate data while each subject stood quietly. Additionally, three subjects performed the following tasks on one force plate: standing on one foot (flat), and standing with raised heels of both feet (on the forefoot). In addition to the standing experimental protocol, two subjects were asked to balance a yardstick in the palm of their hand.

PROGRESS—Data collection and preprocessing have been completed, and initial analysis suggests that during the process of standing, the VCOP is proportional to the ACOM with a time delay, as our model had predicted. The stick balancing activity can also be described by the model. Agreement between the data and the prediction of the model suggests a similarity between human standing balance and human tracking behavior. In standing, the position of the COP tracks the position of COM. This behavior is a tracking behavior that is found in balancing a stick in the palm of one hand. Investigation on how the model applies to standing balance with increasing level of difficulty (i.e., standing with raised heels, or with one foot) is in progress.

RESULTS—The experimental data show that in general, the VCOP follows proportionately the curve of

ACOM with a time delay, as predicted by our model. A coherence function was used to determine the extent to which ACOM is related to VCOP. A coherence of 70 to 90 percent was found on the subjects studied, which suggests agreement with the model. The model revealed a time delay associated between ACOM and VCOP. Autocorrelation analysis is used to compute this delay. Initial estimates for the time delay during the activities investigated fall within the 200 to 450 ms range.

The model has revealed a control strategy and a delay associated with normal standing. Outcomes of this project include possible new approaches for both the clinical screening and evaluation of persons for balance deficiencies, and the evaluation of the balance of prosthesis and orthosis users, which is key to good ambulation.

FUTURE PLANS—We plan to investigate how the model applies to the persons with impaired balance. The investigation may show how the measurements resulting from the model correlate with performance of balance. Our model indicates a time delay associated with standing. Time delays may be an indicator of system performance and stability. Exploration of the effect of time delay is also planned as a topic for future studies.

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Studies of human standing, stepping, and gait initiation (dissertation). Jhoun JH. Chicago, IL: Northwestern University; 1997.

[47] THE EFFECT OF PELVIC OBLIQUITY AND STANCE-PHASE KNEE FLEXION ON THE VERTICAL DISPLACEMENT OF THE TRUNK DURING NORMAL WALKING

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PURPOSE—Conventional wisdom in orthopedics states that the function of pelvic obliquity and stance-phase knee flexion in normal walking is to lower the trunk at its peak vertical displacement, thereby reducing the trunk's vertical excursion and minimizing the energy expenditure of gait. However, kinematic gait data from normal ambulators indicate that these movements are maximum at about the time of toe off and are nearly neutral by the time the trunk reaches its peak vertical displacement during the gait cycle. Therefore, we believe that the roles of pelvic obliquity and stance-phase knee flexion in normal walking may be different from what is generally believed. We measured pelvic obliquity and stance-phase knee flexion in normal ambulators, and calculated the effect of these movements on the trunk's vertical displacement.

METHODOLOGY—We acquired data from three adult male controls with no known gait pathologies at the Children's Memorial Hospital Gait Analysis Laboratory in Chicago, a laboratory that routinely performs clinical gait analyses. Kinematic measurements were made with a Vicon system, and ground reaction forces were measured with two AMTI forceplates embedded in the walkway. The subjects walked at four speeds from about 1.0–2.4 ms. For each of the subjects, three data trials at each of the walking speeds were acquired and processed for our investigation.

RESULTS—Our results showed that in normal walking pelvic obliquity is maximum at about the time of toe-off, and is nearly neutral by midswing. We determined that pelvic obliquity has negligible effect on the vertical excursion of the trunk, which is contrary to what has been widely reported in the literature. The reason for this discrepancy is because pelvic obliquity is out of phase with the trunk's vertical displacement. We observed that the primary effect of pelvic obliquity on the trunk's vertical displacement was to decrease its mean elevation by about 2–4 mm and shift the waveform slightly in phase from where it would have been otherwise. Because normal pelvic obliquity is initiated with heel contact during gait, and reaches a maximum near contralateral toe-off, we believe that pelvic obliquity serves as a physiological shock absorber to reduce ground reaction forces as load is shifted from the trailing to the leading leg, a role which has been suggested in the literature by other researchers. Stance-phase knee flexion in normal walking was found to decrease the vertical position of the trunk by about 10 mm at the slowest walking speeds, and up to 45 mm at the highest speeds. However, as with pelvic obliquity, we observed that the vertical displacement due to stance-phase knee flexion was out of phase with the trunk's vertical displacement due to limb geometry during gait. As a result, the effect of stance-phase knee flexion on the vertical excursion of the trunk was found to be minimal. The phase relationship that stance-phase knee flexion has with the trunk's vertical displacement waveform is nearly identical to that we observed for pelvic obliquity. Based upon our results we believe that, like pelvic obliquity, stance-phase knee flexion plays a critical role in shock absorption during normal walking.

FUTURE PLANS—Both stance-phase knee flexion and pelvic obliquity appear to play significant roles in reducing the magnitude of the force transmitted from the ground to the body in normal walking. By designing prostheses and prosthetic components that will restore, or simulate, the shock-absorbing functions of these physiological movements, we believe that the gaits of persons with amputation may be substantially improved. Implementing new prosthetic designs and fitting techniques based upon our results will involve educating rehabilitation clinicians on the shock-absorbing nature of pelvic obliquity and stance-phase knee flexion, since much of the literature appears to have misinterpreted their role in normal walking.

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[48] GAIT ASSESSMENT FROM SINGLE MARKER MEASUREMENTS

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PURPOSE—Velocity, cadence, and step length have always been important measurements associated with human walking and with assessment of human gait. In this project, we investigated the efficacy and applicability of a simple method of gait analysis that produces several parameters used in gait analysis through the analysis of one marker placed near the body center-of-mass (COM). This method is not a replacement for conventional gait analysis, but may have clinical applications. This work forms the instrumentation foundation for our development of simple methods of gait assessment, such as the Direct Ultrasound Ranging System (DURS).

METHODOLOGY—A marker was placed on the subject's trunk at near the S-2 level. Data were collected and analyzed as several subjects walked naturally. Although simpler instrumentation system may be used, the CODA-3 movement monitoring system was used in the study because of its availability.

PROGRESS—A single marker placed near the COM at the level of S-2 can provide information on the velocity, step length, cadence, spatial and temporal symmetry, rate to achieve steady state walking, lateral and vertical body movement, and some gait initiation parameters. Velocity data were obtained by taking the derivative of position data. Analysis of the occurrence of peaks and valleys of the waveforms from vertical position and forward velocity of the COM provided information on cadence, step length, step duration, and the number of steps to achieve steady walking speed. Temporal and spatial symmetry was obtained by comparing waveforms of successive steps. Gait initiation is a topic of interest by several investigators. Some important parameters related to gait initiation that may be obtained using one-marker analysis include the time and distance needed to achieve steady state walking speed. Passing the instantaneous velocity and acceleration profiles through a very low pass filter provides the profiles of the mean walking velocity and acceleration. These profiles provide information about the kinematics, time and distance necessary to achieve steady-state walking speed from standing.

RESULTS—This study shows the theoretical rationale for one-marker analysis, as well as its convenience, practicality, and usefulness. The amount of data that needs to be gathered in this kind of analysis is minimal, allowing speedy data processing and analysis. We do not suggest that one-marker analysis provides all information on walking, or should replace other existing means of gait analysis, but that it should be seen a convenient means of obtaining practical and useful information about gait. Several results of this work have been applied to DURS.

FUTURE PLANS—Although this method is simple and provides a lot of useful information, further studies to confirm the reliability of the method are needed. We plan to develop models of gait and relate the measured data to the models. Investigation of the clinical significance of the waveforms derived from one-marker analysis is also planned. We will use the results of this work to enhance the development of the DURS.

RECENT PUBLICATIONS FROM THIS RESEARCH

Gait assessment using one-marker analysis. Chan RB, Childress DS. Gait Posture 1995;5(2:175–6.

[49] USE OF JOINT TORQUE, ENERGY, AND POWER IN CLINICAL GAIT EVALUATION

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PURPOSE—Clinical evaluation of the effectiveness of prosthetic feet is essential as new technologies emerge. Recent development in lower-limb prosthetics has been aimed at feet that store energy in mid-stance and return the energy at toe-off to assist the user in propulsion. Joint power is used to determine the amount of energy stored and returned, which is then used to determine a specific foot's clinical efficacy. This project will address the limitations in current methods for power calculation and explore improved methods.

METHODOLOGY—Inverse dynamics has been the primary analysis model used in gait analysis to estimate the net mechanical power and work required to move the body through a gait cycle. However, researchers have recently pointed out the incorrect assumptions of inverse dynamics when applied to ankle-foot devices: the model assumes a rigid foot articulating about the ankle, and there is no accounting for the energy dissipation and recovery in the viscoelastic material of the cosmetic cover.

The Dynamic Elastic Response (DER) foot used for the study contains three carbon-fiber deflection plates for energy storage. Materials testing was performed to determine the mode of deformation and the damping characteristics of the foot. In order to determine the presence of hysteresis or viscoelasticity, the foot was loaded cyclically between 10 and 800 N at 0.5 Hz. A portable x-ray unit was positioned in front of the MTS machine to record medial-lateral images of the foot at various stages of deformation. A known reference length bar was positioned in the field of view to normalize varying degrees of magnification. Images were recorded at these approximate loads: unloaded, 200 N, 300 N, 400 N, 685 N (approximating body weight), and 800 N. The films were digitized and processed using the public domain NIH Image program to obtain deflection angles at incremented vertices along the length of each deflection plate.

PROGRESS—The load-deflection curve for the foot under cyclic loading between 10 and 800 N shows that once a consistent cycle is reached, the loading-unloading cycles form a loop, showing the presence of hysteresis in the foot structure. Representative energy loss in the hysteresis loop for a single cycle was 1,128.31 N-mm. This figure is 14.9 percent of the input energy.

When compared to the image for the unloaded foot, measurement of angle at the vertices superimposed on the large plate shows that deflection occurs along the length of the plates as in cantilever beam loading. Similar results were obtained for each plate at each loading increment. Furthermore, at maximum deflection, the ankle joint center of rotation assumed by inverse dynamics is actually the only rigid portion of this DER foot.

RESULTS—Hysteresis in the foot structure confirms the presence of energy dissipation with each cycle, most likely due to the cosmetic foam cover. Energy dissipation is not accounted for in the inverse dynamics approach. Its presence in the gait cycle can result in erroneous conclusions regarding energy stored and returned by the prosthetic foot. As this factor is prevalent in the literature as a means for comparison of different DER feet, this represents a serious inadequacy.

RECENT PUBLICATIONS FROM THIS RESEARCH

The limitations of inverse dynamics for the analysis of below-knee amputee gait with a dynamic elastic response prosthesis (Abstract). Geil MD, Berme N, Simon SR. Gait Posture 1997;5(2):140.

Quantitative assessment of below-knee amputee gait. Geil MD, Parnianpour M, Berme N, Simon SR. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press, 1997.

[50] DEVELOPMENT OF A GAIT INTERPRETATION, INSTRUCTION, AND REPORT GENERATION SYSTEM

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PURPOSE—Both health care and rehabilitation for orthopedic clients may be improved by taking advantage of the increasingly sophisticated quantitative measures now available for gait analysis. To ensure the effective use of these measures, our goal is to develop a computer-based tutoring and report-generation system. This system can be used to help orthopedic residents and physical therapists gain experience and skill in analyzing various gait dysfunctions, and to develop more informative patient reports for referring physicians.

METHODOLOGY—The Dr. Gait III tutor and report generation system is currently being developed on a Macintosh computer environment using the C programming language. This environment allows users to manipulate multimedia elements such as sound, video, animation, illustrations, and graphical representations easily. Providing data in these formats will support both the instruction of individuals interested in acquiring the skills of gait analysis and the production of detailed client reports for those who manage and provide care.

PROGRESS—A fully functional prototype of Dr. Gait III has been developed and is being subjected to beta testing by orthopedic surgeons and residents, physical therapists, and physical therapy students. This system will also be ported to an IBM environment as evaluation results are compiled and the preliminary system design refined.

The system allows users to enter, review, and annotate data from actual cases. This annotated data and accompanying text segments can be incorporated into a detailed report of progress. Preliminary interviews with orthopedic surgeons revealed that in addition to providing a tutoring system for residents, the ability to maintain and manage client information is an important additional function.

Each screen of data may be annotated in a manner appropriate to the type of data. Text screens provide the capability to change the style (bold, italics, etc.) and color of the text. The colors available have been chosen for saturation and depth to be distinctly identifiable when printed on a grayscale printer.

We are currently developing a suite of teaching cases for which the tutoring aspects have already been authored. In addition, the system may be used to author new cases for which no tutoring has been recorded.

Any item of data, along with its annotations, may be selected for inclusion in the report. This provides a simple method for including annotated data that is not very time-consuming, because many of the annotations can be made automatically. Additionally, text can be generated to accompany some of the findings. Once the data has been noted for inclusion in the report, a procedure is run to build the report in an organized manner based on common templates in a word processor. Further editing of the report is still necessary, but the data is already in place, making it easy to view the substance while writing the discussion.

FUTURE PLANS—Following the completion of the current evaluation, a formal evaluation study is planned. Following this evaluation, the Dr. Gait III system will be distributed for general use as both a case-based interactive learning environment and a client evaluation and care management tool. Further evaluations will accompany this distribution.

RECENT PUBLICATIONS FROM THIS RESEARCH

A multimedia system for generating gait analysis reports. Johnson KA, Simon SR, Smith PJ, Smith JW. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press, 1997. p. 103–5.

Applications of intelligent multi-media technology in human motion analysis. Simon SR, Smith PJ, Smith, et al. In: Harris GF, Smith PA, editors. Human motion analysis: current applications and future directions. New York: IEEE Press; 1996.

Dr. Gait III—a system for gait analysis. Johnson KA, Denning R, Smith PJ, Smith JW, Simon SR. Proceedings of the 19th Annual RESNA Conference; 1996 Jun 7-12, Salt Lake City, UT. Washington, DC: RESNA Press, 1996.

[51] REFINEMENT, EVALUATION, AND DISSEMINATION OF A DIAGNOSTIC AND TREATMENT ASSESSMENT EXPERT SYSTEM FOR THE INTERPRETATION OF WALKING DISORDERS LEADING TO DISABILITY

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PURPOSE—This project involves the continuing development of a diagnostic and treatment expert system for the interpretation of walking disorders leading to disability. Over the past decade, research efforts have been developing tools to assess human gait performance objectively. To assist clinicians, computational methods in analyzing gait could ensure a standardized, high quality level of analysis, decrease the time involved in doing an analysis, provide report-writing support, provide updates for new techniques, and be part of a tool for instruction on gait analysis.

METHODOLOGY—We have been working with a prototype expert system called QUAWDS (Qualitative Analysis of Walking DisorderS) for diagnosing cerebral palsy gait disorders from the multiple sources of raw data used by the gait analysis expert. The major subtasks are: motion deviation identification, muscle fault generation, muscle fault rating, explanatory coverage determination, and determination of overall interpretation. These modules use a combination of associational knowledge (rule-like) and a qualitative model of the physical system.

We are in the process of isolating these and embedding them as decision-support tools within a user-friendly cooperative problem-solving interface, so that a gait analysis expert can easily use any or all submodules of QUAWDS for gait analysis. We are also evaluating the system's performance against human experts, refining the decision-support tools to achieve expert level performance.

PROGRESS—We have nearly completed the transfer of knowledge from QUAWDS to decision-support tools to be embedded in the system. Currently, there are tools for identifying significant findings with respect to joint angle graphs, range of motion, time and distance data, and EMGs. We have programmed additional functions that can be used to pull information from the AI decision-support tools into a report. For example, the motion findings can be output in both textual and graph form, and the text has been refined to read in a more human-like manner so that they can be incorporated into a report with little or no modification. We have also written code to determine the muscle faults associated with a particular deviation and we are currently developing the interface to integrate this function into the interface. Some of the errors in QUAWDS' performance were known to be related to the method of motion finding determination; therefore, we have been experimenting with alternative methods of finding determination such as Sutherland's prediction regions.

RESULTS—The system is being beta-tested at several sites. Providing a single place for data to reside for gait analysis is proving to be quite a useful concept for both teaching gait analysis and facilitating clinical report generation. The decision-aid tools that have been provided up to this point seem to be useful and fairly accurate. Another benefit is the ability to explore other methods for accomplishing subtasks of gait analysis and comparing the outputs easily. This eventually leads to a better method for performing gait analysis as well as better support for the people currently doing (or learning to do) that analysis.

FUTURE PLANS—We are working to add new functionality to the system based on other research into the clinical significance of data analysis types for gait analysis. As we determine new categories of findings based on our research into torques, powers, moments, time/distance parameters, and the like, decision-aid tools will be developed and added to the system. These tools will improve both the functioning of the system as well as our understanding of the process of gait analysis.

RECENT PUBLICATIONS FROM THIS RESEARCH

A multimedia system for generating gait analysis reports. Johnson KA, Simon SR, Smith PJ, Smith JW. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press, 1997. p. 103–5.

Applications of intelligent multi-media technology in human motion analysis. Simon SR, Smith PJ, Smith, et al. In: Harris GF, Smith PA, editors. Human motion analysis: current applications and future directions. New York: IEEE Press; 1996.

Dr. Gait III—a system for gait analysis. Johnson K, Denning R, Smith PJ, Smith JW, Simon SR. Proceedings of the 19th Annual RESNA Conference; 1996 Jun 7-12, Salt Lake City, UT. Washington, DC: RESNA Press, 1996.

[52] THE INFLUENCE OF FATIGUE ON EMG AND IMPACT ACCELERATION IN RUNNING

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PURPOSE—This research was aimed at analyzing the effects of fatigue on the ability of the human musculoskeletal system to attenuate the heelstrike-generated shock waves in running and to correlate any existing changes in the EMG signal with other fatigue measures.

METHODOLOGY—Each subject is instrumented with a light-weight accelerometer placed externally over the tibial tuberosity and with two pairs of bipolar surface EMG electrodes placed over the quadriceps and gastrocnemius. The subjects run on a treadmill for 30 min at a speed corresponding to their individual anaerobic threshold level, while the acceleration and EMG data are sampled. Fatigue is monitored by the respiratory end-tidal CO_2 pressure.

Data processing is simplified, due to the constant speed of running during each test. Software is developed that utilizes the given speed and location of the first heel strike. After this, it automatically processes and detects all consequent occurrences of heel strike.

The analyzed variables are the maximum amplitudes of the accelerations recorded at foot strike on the tibial tuberosity; mean and RMS of the EMG signal in the time domain, mean and median frequency of the same signal in the frequency domain, and $PETCO_2$. For each subject, the maximum accelerations recorded in one file are measured and averaged. After this, the acceleration data are normalized with respect to the record at the beginning of the experiment.

The obtained data are processed via conventional statistical routines available in ‘‘MATLAB.’’ Differences between results were tested (t-test) and the level of significance determined at $p<0.05$.

RESULTS—The obtained results show that whenever general fatigue occurred, the amplitude of acceleration signal steadily increased. However, in both the time and frequency domains, EMG did not correlate with fatigue. Thus, one may conclude that when fatigued, the human musculoskeletal system becomes less capable of handling the heelstrike-induced shock acceleration.

FUTURE PLANS—It is intended to extend this study to include different fatiguing protocols. EMG measurements will be extended to include the tibialis anterior and hamstrings muscles, in addition to the already monitored gastrocnemius and quadriceps muscles. Kinematic measurements will also be made during the experiments. A biomechanical model of the lower limb will be developed by which the variations of the elastic and damping coefficients of the segments can be evaluated as a function of the fatigue level.

RECENT PUBLICATIONS FROM THIS RESEARCH

The influence of fatigue on EMG and impact acceleration in running. Mizrahi J, Voloshin A, Russek D, Verbitsky O, Isakov E. Basic Appl Myol 1997;7:119–26.

[53] ASSESSMENT OF AMBULATION MOTION PARAMETERS FOR CLINICAL EVALUATION

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PURPOSE—The overall goals of this work are to develop simple motion parameters and indices for general and specific patient populations; evaluate the computational complexity of such parameters while investigating sources of error and variability; examine the feasibility of implementing these parameters in clinical data processing; assess the usefulness of these parameters in diagnosing motion disorders, prescribing interventions, evaluation of long term prognoses, and assessing disability levels; and finally, develop a database of normal values for these parameters.

METHODOLOGY—At this phase of the project, we are developing parameters that will assist orthopedic surgeons who perform musculotendon lengthening in children with cerebral palsy (CP) in determining the appropriate amount of lengthening. Following appropriate modeling of the kinematics of each of the joints of the lower limb, the kinematic and kinetic information with respect to the musculotendon units of interest (e.g., moments, moment arms, forces and lengths, and strains) can be determined at different joint positions. The kinetic data can be estimated as they relate to one or several musculotendon units. Our analysis indicates that the length and force outputs determined for each individual musculotendon unit are the most acceptable variables to be investigated. We have also been able to use our already existing database as well as information collected from recent studies in an effort to combine pre- and postsurgery data to investigate the effects of musculotendon unit lengthening.

PROGRESS—We are incorporating motion data from gait evaluations from persons with CP who are to undergo different treatment procedures, such as either the use of ankle foot orthotics or derotational osteotomies, to determine the effects of these treatments also. Our initial results indicate that surgery, and in particular musculotendon lengthening, has the most dramatic effects.

In addition, in order to extend the capabilities and theoretical reliability of the musculoskeletal model, we have proceeded in specific modeling of the knee joint. Our approach involves consideration of equilibrium conditions when solving for the knee joint moments, moment arms, and musculotenon forces. The mathematical formulation of the improved knee joint model has been completed.

In order to establish a database for the muscle strengths of individuals without any pathology for comparison, we performed gait evaluations on 14 controls under different conditions, rested and fatigued. Our results indicate that individual musculotendon groups of interest operate at specific regions on Hill's curve.

Another objective of this project has been the determination of the threshold level of spasticity. We have established the importance of the careful processing of the electromyographic signal, demonstrating that even with maximum isometric contractions, the signal will vary depending on the task that the specific musculotendon unit is required to perform.

However, accurate identification of the threshold level of spasticity, and accurate identification of the individual muscle strengths presupposes the ability to estimate individual muscle forces. Toward this end we have constructed an EMG-driven model whose final output is a cocontraction, or spasticity, index. Our theoretical and mathematical formulation of the EMG-driven model has been completed. and it is being implemented in computer code. In the very near future data will be collected from maximum of fourteen subjects to validate the model.

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A functional evaluation of the fasciocutaneous free flap for soft tissue defects on the weight bearing surface of the foot. Kamaleson M, Nappi JF, Lubbers L, et al. Proceedings of the 11th Annual Meeting of the American Society for Reconstructive Microsurgery; 1996, Tucson, AZ.

Functional integrity of fasciocutaneous flaps: biomechanical evaluation of selected kinetic variables. Karakostas T, Kamaleson M, Quesada PM, Simon SR. In: Engin AE, editor. Proceedings of the Third Biennial European Joint Conference on Engineering Systems Design and Analysis, 1996 ASME International, Montpellier, France; 1996. New York: The American Society of Mechanical Engineers; 1996. Vol 5. p. 43–50.

[54] EFFECT OF AN INDUCED LEG-LENGTH DISCREPANCY ON GAIT BIOMECHANICS

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Sponsor: *None listed*

PURPOSE—A major goal is to better understand the physiologic factors involved in the compensation for the inequality of lower limb lengths. It is desired to document at what levels of leg-length inequality does compensation at the hip occur, and what overall changes occur in the mechanics of gait. With this information, pathologic changes that occur in the hips, lower back, and lower limbs due to compensation for leg-length inequality may be better understood. This may facilitate inferences on effective treatment options.

METHODOLOGY—Six to 10 controls with documented normal leg length (using both the ASIS to floor method and ASIS to medial malleolus methods to assure no structural or functional pre-existing pathology) will be tested by completion of the study. Many have studied the clinical assessment of degree of leg-length discrepancy, and we choose the ASIS to medial malleolus because it seems to be the most rigorously tested. While some claim that ASIS to lateral malleolus can detect functional leg-length inequalities, this technique has not been as well demonstrated in the literature. Two mechanisms of leg-length discrepancy are used: a tapered heel lift (variable thickness with maximum thickness of 1.27 cm at the heel) is placed in one shoe, and a full shoe lift (constant thickness of 1.27 cm) is placed under the shoe. Each subject is given a chance to accommodate to the test condition before data are recorded and is tested without any orthotic as well. Temporo-spatial foot fall parameters (such as stride lengths and times, stance/swing lengths and times, step lengths, and walking velocity) as well as ipsilateral hip, knee and ankle kinematics, and kinetics are recorded. Upon completion of the test session, the subject is given the partial lift to wear during all activities for 2 to 3 wks. Each subject is then re-tested as outlined above in just the heel lift and no lift conditions.

PROGRESS—Several subjects have been tested to date; testing and analysis is ongoing.

PRELIMINARY RESULTS—There appear to be statistically significant differences in lower limb kinematics and kinetics of the longer limb. Differences are noted between the lifted limb and same limb when no orthotic is used to induce a leg-length discrepancy, as well as between the lifted limb before and after the accommodation period.

Specific changes for a very limited number of subjects have been noted in pelvic obliquity and range of motion, pelvic rotation, hip flexion, hip adduction and range of motion, hip rotation, and various forces. Some of the changes seem to correlate with the expected responses to a lift (such increased ipsilateral hip flexion and pelvic obliquity) where as others do not. There is undoubtedly a complex series of interactions that give rise to the mechanisms individuals use to compensate for the intervention. An insufficient number of subjects has been tested so far to be able to speculate about trends in the methods of compensation.

FUTURE PLANS—Differences between short- and long-term changes in the biomechanics of gait in compensation of leg-length discrepancy and the characteristics of leg-length discrepancy that lead to pathologic changes in the hip and back are areas of focus.

C. Other

[55] WHEELCHAIR PROPULSION PERFORMANCE IN YOUNG, MIDDLE-AGED, AND ELDERLY

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PURPOSE—The purpose of this program is twofold: 1) to investigate how age affects wheelchair performance for lower-limb impaired wheelchair users; and 2) to test a specific exercise intervention for its effectiveness in reducing potentially injury-producing biomechanical characteristics and excessive physiologic stresses.

METHODOLOGY—Anthropometric and muscle strength measurements, neuromuscular assessments, and wheelchair propulsion testing were performed before and following exercise training (stretching, strengthening, and aerobic training three times weekly for 6 wks). Shoulder, elbow, and wrist joint kinetics (joint moments and joint reaction forces) were calculated from 3-D motion and handrim force data. Changes with training in all variables were statistically tested using repeated measures ANOVAs (pre/post vs. unfatigued/fatigued) with a 0.05 level for significance. Interaction effects were further analyzed with paired t-tests and a Bonferroni correction for multiple comparisons.

PROGRESS—Twenty wheelchair users completed the study. Eleven additional subjects completed pretesting only. Seven nonusers (controls) have been tested for database comparisons.

PRELIMINARY RESULTS—Twenty subjects (age 44±11 yrs; weight 78±20 kg; spinal cord lesion level T2-L5 and multitrauma; 16 male, 4 female; wheelchair users for 16±10 yrs) completed the study. Significant results of the training intervention on all measures follows. Anthropometric and temporal measures were unaffected by training. Eccentric isokinetic strength increased for wrist flexors (38.5 percent), extensors (27.8 percent), radial deviators (30.1 percent) and ulnar deviators (32.5 percent). Joint kinematic changes included a 3.2 percent increase in maximum elbow extension and a 6.5 percent increase in maximum trunk flexion during the entire wheelchair propulsion cycle. The increase in trunk forward flexion was evident during both contact (6.1 percent) and time of release (6.9 percent), and increased 8.9 percent in the fatigued condition at the post-test compared to the pretest. Handrim kinetic changes included an increase in the maximum propulsion moment (1.1 percent) and in the resultant moment (1.2 percent). Joint kinetic changes included an increase in the shoulder flexion moment (Mz) of 16.2 percent and shoulder anterioposterior shear force of 16.4 percent. The timing of muscle activity as determined from EMG changed significantly for the middle trapezius which came on 16.1 percent later in the cycle and reached peak activity 13.1 percent later, and shut off 10.9 percent later.

FUTURE PLANS/IMPLICATIONS—Initial findings indicate that specific training for wheelchair users can improve wheelchair propulsion mechanics, possibly decreasing susceptibility to overuse injury. Further investigation of joint stresses is continuing. Three additional controls will be tested before completion of the study for comparison. A videotape of the exercise training program will be produced.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Estimation of body fat by skinfold measurement in wheelchair users. Keyser RE, Russell PJ, Rodgers MM, Gorman PH. Am Phys Ther Assoc Sect Res Newslett 1997;29(2):19-20.

Kinematic and kinetic effects of training in wheelchair users. Rodgers MM, Gorman PH, Russell PJ, Keyser RE. Am Phys Ther Assoc Sect Res Newslett 1997;29(2):19.

[56] QUANTIFICATION OF MUSCULAR AND TENDINOUS FORCES OF THE HAND DURING STATIC EFFORT

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Sponsor: *Conseil de recherches médicales du Canada; Wright Medical Technology*

PURPOSE—The purpose of this project is to develop a valid biomechanical model of the human finger, quantifying the muscular and tendinous forces and joint constraint forces exerted on the structures of the hand during static efforts.

METHODOLOGY—We propose a new method to quantify muscle forces based on *in vivo* measurements and an anatomical model of the finger. The experimentation will be realized in persons receiving a bone plate following a transverse fracture of the metacarpal or phalangeal bone. The regular bone plate will be temporarily removed and replaced by a sensor, allowing measurements of force and moments of force exerted at the site of the fracture in four degrees of freedom (forces in tension-compression and moments of force in the ventro-dorsal, medio-lateral, and rostro-caudal axes of the bone). The subjects will receive a block of the nerves innervating the tested finger and will be asked to perform static efforts at the distal tip of the finger in the flexion-extension plane, while forces and moments of force on the bone will be measured. These measurements will be obtained with the finger in two positions, that is, the metacarpo-phalageal joint (MCP) in extension and in flexion. A lateral and dorsal X-ray of the finger will be realized to quantify the location of the transducer relative to bone structures. Once the measurements are completed, the sensor will be removed and the surgery completed as usual. Using the force and moment of force values measured during the surgery and moment arm values estimated using the geometrical model of the finger, it will be possible to solve independent equations of static equilibrium and to quantify muscular and tendinous forces.

PROGRESS—To date, the experiments have been conducted on 10 persons, 4 in the preliminary experiments and 6 using the new protocol and apparatus. The force in compression, as well as the moments of force were measured in three axes, since a gap between bone segments ensures that these forces and moments of force are transmitted through the transducer. In order to compare the results across subjects, the forces and moments of force measured by the transducer were expressed as in units of applied force at the fingertip. We are now analyzing the results and calculating muscle forces based on the geometrical model of the finger.

PRELIMINARY RESULTS—The results in all subjects indicate that an increasing compressive force and flexor torque were developed progressively as the external force exerted at the tip of the finger increased. The ratio of compressive force per unit of distal force measured at the phalanx and metacarpal varies between 3.7 and 9.8 with a mean of 5.4 (SD=2.2) during a isometric flexion with all joint in extension.

Using these *in vivo* measurement and our anatomical model of the finger, the values of the muscular and tendinous force acting on the bone are slightly higher than those estimated from other studies using biomechanical modeling of the finger an optimization technique.

FUTURE PLANS—It is expected that this model will provide major clinical impacts in diverse areas, such as hand surgery and rehabilitation. As short-term goal, we believe that repeating the experiments in six to eight additional subjects would help to precisely establish the torque and force patterns. As a long-term goal, it is planned to evaluate or optimize the design of bones, plates, or hand implants using this model.

[57] DETERMINING SOFT TISSUE MATERIAL PROPERTIES FOR THE PURPOSE OF FINITE ELEMENT MODELING OF THE RESIDUAL LIMB IN TRANSTIBIAL AMPUTATION

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Sponsor: *National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 22202*

PURPOSE—Finite element (FE) modeling is a potential tool for designing improved prosthetic sockets, based on a prescribed socket/residual limb stress distribution. Currently, the accuracy of modeling the socket/residual limb system has been limited by inaccurate representation of soft tissue material properties. An indentor test has been used by previous investigators to estimate bulk tissue modulus values at various locations, but the accuracy of this method is limited because only a small number of sites can be tested. Also, the indentor test only gives an average bulk modulus at the test site and yields no information on how material properties vary radially. Our goal is to demonstrate that we can use CT scans and their grayscale values to obtain a good estimate of tissue modulus values throughout the whole limb.

METHODOLOGY—It is our hypothesis that a relationship can be found between CT scan grayscale values and the Young's modulus of the soft tissue. The grayscale distribution method involves using force/displacement data obtained from CT scans of a residual limb deformed by an ICECAST pressurized casting apparatus. Using metallic surface markers, CT scans can be used to track hundreds of surface points. An FE model with surface nodes that correspond to marker locations can be developed from the CT scan images. Testing average gray scale value is found for each element and an estimate of Young's modulus is assigned. The experimental loading conditions are then simulated and the FE surface marker displacements are compared to the experimental surface marker displacements. The coefficients of the transformation equation are optimized, based on the surface marker displacement error. The purpose of this study is to find the transformation relationship that will most accurately convert grayscale values to Young's modulus values.

PROGRESS—Thus far, theoretical modeling and testing of a physical model have been completed. Theoretical modeling of a residual limb was used to see whether optimization could be used to find material properties using a surface displacement error criterion. With theoretical modeling, no experimental measurements were obtained. Instead, material properties are distributed through a simulated experimental FE model and "experimental" displacements are calculated. Using these displacements, an attempt was made to solve the material properties of the model. The success of the solving procedure was then evaluated.

A physical model was developed to further test our procedure for solving material properties. This type of testing differed from the theoretical model testing in that external sources of error were present, including digitizing error, inaccurate boundary condition representation, and error inherent to FE modeling. The objective was to see whether the material-property-solving procedure would be adversely affected by these error sources. The physical model was based on homogeneous materials with known material properties, to allow comparison with the material property solutions. CT scans taken of the model under various pressures and displacements were measured. The optimization procedure was applied and the accuracy of the solution assessed.

RESULTS—Theoretical model testing proved the potential for using an optimization procedure to solve material properties based on surface displacement error. Also, the physical model testing proved successful. The material property of the physical model was solved within 1.5 percent of the actual value. The overall surface displacement error was less than 17 percent, when errors were weighted by the magnitude of their displacements. When all surface errors are weighted equally, the surface displacement error increases to 44 percent. Areas that had small displacements showed higher errors, indicating that digitizing error can adversely affect results. If the digitizing error is of the same magnitude as the displacement, predictive accuracy deteriorates.

FUTURE PLANS—Our next test will be conducted on a human subject. We have received Institutional Review Board approval and plan to initiate testing in the near future.

[58] STANDING SWAY: KINEMATICS AND DYNAMICS FROM FORCEPLATE MEASUREMENTS

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Sponsor: *The Segal Foundation and the Fund for the Promotion of Research at the Technion, Israel*

PURPOSE—We are working to develop a model for the estimation of the kinematics and dynamics of the lower extremities in standing sway from bilateral forceplate measurements.

METHODOLOGY—A three dimensional, five-segment four-joint model of the human body is used to describe postural standing sway dynamics. Force-plate data of the reactive forces and centers of pressure are measured bilaterally. By applying the equations of motion to these data, the transversal trajectory of the center of gravity (CG) of the body is resolved in the sagittal and coronal planes. An inverse kinematics algorithm is used to evaluate the kinematics of the body segments. The dynamics of the segments are then resolved by using the Newton-Euler equations, and the model's estimated dynamic quantities of the distal segments are compared with those actually measured. Differences between model and measured dynamics are calculated and minimized using an iterative algorithm to re-estimate joint positioning and anthropometric properties.

RESULTS—The above method was illustrated on a group of 11 nonimpaired controls. The average relative errors were: 0.34 (±0.25) percent for the vertical forces; 1.97 (±1.12) percent for the ML forces and 15.7 (±14.8) percent for the torques in the sagittal plane. Relatively large errors were found for the AP forces 62.7 (±64.2) percent and the torque in the coronal plane 33.4 (±43.8) percent. The angular displacements in the right ankle were found to be in opposite phase with the right hip, both in the coronal and sagittal planes. Similar angular displacements were found on the left side.

The results indicate that the relative errors obtained in the final iteration are of the same order of magnitude as those reported for closed loop problems involved in direct kinematics measurements of human gait.

FUTURE PLANS—It is intended to extend the developed model to enable evaluation of the muscle forces crossing the joints. EMG measurements of the major muscles of the lower limbs will be performed and incorporated in the solution procedure of the model.

RECENT PUBLICATIONS FROM THIS RESEARCH

An iterative model for estimation of the trajectory of center of gravity from bi-lateral reactive force measurements in standing sway. Levin O, Mizrahi J. Gait Posture 1996;4:89–99.

[59] BILATERAL DEFICIT DURING KNEE EXTENSION

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Sponsor: *University of New Brunswick Research Fund*

PURPOSE—The project studied the reproducibility, reliability, effect of contraction velocity, and neuromuscular control of bilateral and unilateral maximal voluntary contractions.

METHODOLOGY—In order to understand the coordinated functioning of the neuromuscular system, we need to know how it functions during a multitude of specific conditions, such as when a coordinated task involves one limb (unilateral) as compared to the same task performed with both limbs simultaneously (bilateral). To quantify the relative contributions of the unilateral and bilateral performances bilateral ratios (BLR) are calculated.

RESULTS—The reproducibility, reliability and the effect of contraction velocity on BLRs during dynamic omnikinetic maximal knee extensions were assessed. In summary, the peak torque BLRs and knee angle BLRs were similar to previous literature which employed isometric contractions. In addition the intra- and inter-test reliability of all BLRs was extremely high ($r>0.95$). Contraction velocity caused BLR to decrease; that is, the force generated during bilateral contractions decreased more than during unilateral contractions. Furthermore the relationship between knee angle and BLR was perturbed by contraction.

FUTURE PLANS—We plan to investigate the neuromuscular control differences between bilateral and unilateral contractions by recording myoelectric signals from the quadriceps and hamstring muscles.

III. Functional Assessment

[60] OPTOKINETIC TESTING FOR DIAGNOSIS AND REHABILITATION OF BALANCE DISORDERS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C691-2RA)*

PURPOSE—The purpose of this study is to generate data on postural sway induced by horizontal optokinetic stimulation in subjects standing on a fixed platform. Postural sway consists of forward-backward and lateral motions, largely about the ankle joints. Sway induced by horizontal optokinetic patterns has not been studied extensively and may provide a challenge to the vestibular and proprioceptive systems, thereby extending the diagnostic value of fixed-platform posturography.

METHODOLOGY—Basic audiologic evaluations and vestibular function questionnaires were completed for each subject. The posturography system consists of a fixed platform with two independent foot plates with force transducers that resolve the forward-backward and lateral changes in the center of force of a standing subject; a 180° curvilinear projection screen, 1 m from the subject; a shadow projector for visual stimuli; and a support harness to prevent falls. Postural sway is recorded with eyes closed, eyes open, and optokinetic stimuli moving at 20, 40, 60, 80, and 100°/s to the right or left. The moving background consists of a random bar (1×8° visual angle) optokinetic pattern covering 180° in the horizontal plane and 40° in the vertical plane. Each trial consists of a 30 s period of testing, followed by a 30 s rest period. Optokinetic stimuli are presented binocularly and randomized to prevent order effects. Subjects are given an alerting task to maintain vigilance and instructed to stand in a relaxed vertical posture, hands at their sides and looking toward the screen.

Postural sway is measured as changes in "center of force," a time-varying vector defined in the horizontal plane, and computed as a weighted average of the output from six force transducers (three in each foot plate). Data are transferred to a spreadsheet program for analysis and displays of positional sway and sway velocity.

PROGRESS—Testing has been completed on 133 subjects, of whom 69 have hearing normal for their age and no complaints of dizziness; 9 reported dizziness/vertigo; 3 were postsurgical for acoustic neuroma removal; 10 participated in a test-retest protocol; 15 had a sensorineural hearing loss, and 27 completed a pilot study to determine the influence of exercise on balance in the well elderly.

RESULTS—Statistical analysis of the group with normal hearing for their age and normal vestibular function revealed no significant differences in balance as a function of age. Subjects with sensorineural hearing loss revealed no statistically significant differences from the normal control population. Of the 9 subjects with vestibular complaints, diagnoses at the time of testing included BPPV, Meniere's disease, cervical sprain, history of drug/alcohol abuse, labyrinthitis, peripheral neuropathy, and otitis media. Only 3 subjects (labyrinthitis; peripheral neuropathy; otitis media) fell outside the normal range in the eyes open, closed, and/or the 60 left condition. Although an interesting pattern of responses was seen within the remaining six subjects, their responses fell within two standard deviations of the normal mean. Analysis of the data as a function of the relative relation between conditions (eyes open, closed, stimulus left and right) may improve the diagnostic application of this protocol. Analysis of test-retest and post acoustic neuroma removal subjects has not been completed. Data analysis for the 27 subjects who completed the exercise protocol revealed significant changes in single limb support (i.e., eyes open, standing on left leg and right leg, and eyes closed, standing on left leg).

Preliminary results from all the study groups suggest that evaluation of postural sway could be used for diagnostic evaluation, post-surgical monitoring of vestibular compensation, and as a possible indicator for individuals at risk for falls in the well elderly.

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Postural adjustments produced by moving visual (horizontal optokinetic) patterns. Blanks RHI, Fowler CG, Zizz CA, Williams KE. J Am Acad Audiol 1996;7:39–48.

[61] VIDEO-BASED FUNCTIONAL PERFORMANCE ASSESSMENT AND TRAINING TOOL: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B2047-PA)*

PURPOSE—The clinical objective of the Functional Performance Assessment and Training (F-PAT) project is to examine the effectiveness of a personalized home-use videotape, containing footage of the client performing transfers incorrectly and correctly in the clinic, compared to traditional instructional materials. The technical objective of F-PAT is to develop a simplified computer-based data and video-manipulation software tool to aid clinical professionals in the process of developing annotated, graphics-enhanced video for clinical assessment and client training. In this project we are using F-PAT to enhance the early rehabilitation of people with cerebral vascular accident (CVA or stroke) through personalized, function-oriented, multimedia-based client and caregiver training. The initial inpatient rehabilitation period after stroke relies heavily on therapist-intensive, hands-on instruction. Afterward, the recovery process continues largely in the home with family and caregivers, with the extent of carry-over of the earlier therapy training having a significant effect on the course of recovery. Efforts to bring the rehabilitation expertise to the home rely on texts, brochures, mass-produced instructional videotapes, home therapy, and, when possible, in-clinic training of family members. In this project, we apply modern and proven concepts of multimedia training to the practice of rehabilitation through personal videotape-based instruction.

METHODOLOGY—For the 1-year pilot project, we hypothesize that the therapist, using commercial video and office computer hardware and software, will be able to create a personalized videotape from video clips of persons performing transfer tasks. The tape will be used subsequently in their home therapy program.

PROGRESS—In collaboration with clinicians at the Comprehensive Rehab Program (CRP), we have defined the types of transfers appropriate for the F-PAT videotaping, based on the current procedure for training people to do transfers. We are compiling critical factors and other relevant data to provide the right information via the videoclip voice-overs. The project staff has developed a template, using a video digitizing and editing computer program, to perform videoclip cataloguing and computer-based videoclip manipulation so that a final videotape, containing personalized information, overlaid graphics, and spoken instruction, can be produced by the therapist with some knowledge of video-editing techniques. A complete first videotape of generic transfers performed by a physical therapist is currently under production.

PRELIMINARY RESULTS—The F-PAT computer database has been modified to be entirely WWW-based (http://guide.stanford.edu/Projects/FPAT/intro.html), so that clinicians with the appropriate password can view a patient chart on-line, complete with videoclips. Using multiple windows, videoclips from different points in time or from different patients can be compared, and the therapist can make review notes and generate patient progress reports.

FUTURE PLANS—Patients in the CRP are being screened by the staff for possible invitation to participate in this study. As per the grant proposal, we will invite 15 people in the upcoming months to receive one of three types of information packets for their take-home instruction in transfers. The clinical evaluation of the effectiveness of these packets will conclude this pilot project.

In future, we plan to test the hypothesis that the personalized videotape will be more effective in promoting retention and accurate training than conventional instructional materials. We will test this hypothesis by the qualitative analysis of client, caregiver, and clinician satisfaction with F-PAT and by quantitative analysis of the impact of F-PAT on clinician time and of transfer-related accidents in the home occurring to the person who has had a stroke as well as to family members and caregivers.

RECENT PUBLICATIONS FROM THIS RESEARCH

Individualized video-based stroke rehabilitation home program. Shafer D, Van der Loos HFM. Proceedings of the 19th Annual RESNA Conference; 1996 Jun 7-12, Salt Lake City, UT. Washington, DC: RESNA Press, 1996. p. 89-91.

Integrated video and computerized functional assessment. Shafer D, Van der Loos HFM. Proceedings of RESNA International '95; 1995 Jun 9-14; Vancouver, BC. Washington, DC: RESNA Press; 1995. p. 146-148.

[62] POST-STROKE REHABILITATION: A PILOT STUDY

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PURPOSE—This research intended to answer the question: does intensive physical therapy training improve long-term outcome after stroke? The majority of stroke survivors have minimal to moderate deficits. These persons are physically deconditioned and have a high prevalence of cardiovascular risk factors that may be potentially modifiable with exercises. However, they receive the least amount of rehabilitation and may not recover to an optimal level. For the most part, physical interventions for stroke are targeted to functional training such as transfers, gait, dressing, and weight-bearing activities: rarely do they include a cardiovascular training component. Exercise studies in geriatric populations suggest balance, strength, or endurance programs have been successful in modifying impairments and functional deficits. No study has ever combined all three components (strength, balance, and endurance) into one intervention program for the elderly or individuals with stroke. The purposes of this pilot study were: 1) to develop a balance, strength, and endurance program based on principles of exercise physiology and motor learning and to deliver it in the home to individuals with mild or moderate strokes; 2) to evaluate the feasibility of recruitment and retention; and 3) to assess the effect of the interventions.

METHODOLOGY—This was a randomized, controlled pilot study. Twenty persons with minimal and moderate stroke impairment (mean Orpington Score 2.7, mean age 67, 11 RCVA, 8 LCVA, 1 Brainstem; 11 males, 9 females; 14 whites, 6 African-Americans) who had completed inpatient rehabilitation and who were 30 to 90 days post-stroke were randomized to usual care or to a therapist-supervised 8 week, thrice-weekly, home-based exercise program of progressive strength, balance, endurance, and bimanual exercises. The control group received usual care as prescribed by their personal physicians. Baseline and post-intervention assessments included the Fugl-Meyer Motor Assessment, Barthel ADL, Lawton IADL, Medical Outcomes Study-36 Health Status Measurement. Functional assessments of balance and gait included 10-m walk, 6-min walk, and Berg Balance Scale. Upper extremity function was evaluated with the Jebsen Hand Test.

PROGRESS—We contacted 22 patients who met study criteria; 2 refused to participate. No subjects dropped out of the study. Subjects tolerated the 1.5 hour intervention and were able to progress in intensity and duration of exercises. Clinical staff were cooperative in monitoring usual care.

RESULTS—The intervention group tended to improve more that the control group in motor function, (Fugl-Meyer UE median change score 10 vs. 5), Fugl-Meyer LE 5 vs. −0.5) gait velocity (median change 0.27 m/sec vs. 0.11 m/sec), 6 min walk (164 ft vs. 108 ft), Berg balance score (7.5 vs. 5) and MOS physical function (22.5 vs. 5). There were no trends in differences in change scores for Jebsen hand scores, Barthel ADLs, and Lawton IADLS.

IMPLICATIONS—This study demonstrates gains in recovery due to specific intervention programs to improve strength, balance, endurance, and bimanual activities. The preliminary findings are important because they demonstrated that a very specific intevention in mild and moderate patients may enhance recovery beyond that which occurs spontaneously. The functional consequences of these gains are not known and will require a larger sample size where interactions may be tested. Some important interacting factors may be depression, comorbidities, and self-efficacy.

[63] DEVELOPMENT OF QUALITY OF LIFE MEASURES FOR USE IN DYSPHAGIA

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C2016-RA)*

PURPOSE—We seek to conceptualize, develop, and validate a subject-based quality-of-life and quality-of-care tool specific for persons with dysphagia. This tool should be of value in outcomes research, clinical trials, health services research, and quality assurance.

METHODOLOGY—The project is taking place across three phases of investigation:

Phase I. We obtained qualitative data, using focus groups, on quality-of-life and quality-of-care outcomes from dysphagic persons and their caregivers. Focus groups are small, carefully planned discussion groups guided by an experienced facilitator with the objective of comprehending participant's experiences on a given topic. Focus groups are ideal for understanding perceptions of disease and treatment because group interaction tends to produce insights that would not surface in individual interviews. Persons with dysphagia were recruited at VA hospitals and affiliated university medical centers in Madison WI and Chicago IL. Phase I activities include development of the focus group agenda, subject recruitment, conduct of the focus groups, and data analysis. Using the focus group data, a large number of questionnaire items will be generated and a standardized, condition-specific questionnaire (SWAL-QOL) that measures experiences of health outcomes of persons with dysphagia will be constructed.

Phase II. We shall pretest the SWAL-QOL upon dysphagic subjects in Madison WI, Chicago IL, and Tomah WI, and conduct preliminary psychometric analyses. The SWAL-QOL will be revised on the basis of these analyses, both to reduce the length of the tool and to improve the quality of retained items.

Phase III. We shall field test the revised SWAL-QOL and conduct thorough psychometric tests. A total of 400 completed surveys will be needed because many of the psychometric tests are based on large-sample statistics. The field test will take place across five VA hospitals and affiliated university medical centers in Madison WI, Chicago IL, Little Rock AR, Houston TX, and Long Beach CA. These sites have active swallowing programs and can contribute a diverse mix of subjects. In the final 6 mo, we will develop a User's Manual and submit manuscripts on the SWAL-QOL for peer review.

PROGRESS—All of Phase I activities have been completed. Phase II activities will be completed in the first month of 1998, and Phase III activities will begin February 1998.

RESULTS—We conducted 13 focus groups (11 in Madison WI and 2 in Chicago IL) to obtain qualitative data on quality-of-life and quality-of-care outcomes from persons with dysphagia and their caregivers. All totaled, our focus group participants included 45 subjects across 9 groups and 15 caregivers across 4 focus groups. A total of 470 pages of transcripts were derived from all 13 groups. These transcripts were carefully analyzed by several different scientists, and a full-day group-consensus meeting was held among study investigators to delineate the major conceptual dimensions for the SWAL-QOL (based on the participant perspective as well as clinical judgment). From the transcripts and our conceptual blueprint, hundreds of questionnaire items were written to represent each domain, using the subjects' own words and conceptions to form the content of the question. These questions underwent dozens of iterations of revisions to yield a ''pilot'' survey of 192 questions. This preliminary version of the SWAL-QOL was fielded in autumn 1997. We obtained 106 usable pilot surveys. Psychometric analyses are currently underway to identify the most discriminating and highest quality items for inclusion in the final version of the SWAL-QOL, which will undergo extensive psychometric validation, including biomechanical criteria, spring 1998. We expect the SWAL-QOL to be ready for widespread dissemination in summer 1999.

RECENT PUBLICATIONS FROM THIS RESEARCH

Generic health measurement: past accomplishments and a measurement paradigm for the 21st century. McHorney CA. Ann Int Med 1997;127(8):743–50.

[64] CHARACTERIZATION OF GLOBAL SYNKINESES IN HEMIPARETIC SUBJECTS USING STATIC BI-ARTICULAR MULTIDIRECTIONAL DYNAMOMETRY AND ELECTROMYOGRAPHY

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Sponsor: *Fonds de la recherche en santé du Québec (FRSQ)*

PURPOSE—Global synkineses (GS) are unvoluntary movements of the affected limbs occurring during forceful contractions on the nonaffected side of hemiparetic subjects (HS). GS hinder the execution and coordination of voluntary movements in HS. Although it is generally considered that the capacity of these persons to control GS is an index of their motor performance, few studies have used quantitative measures to characterize them.

METHODOLOGY—A bi-articular dynamometer allowing the simultaneous measurement of multidirectional torques exerted at the shoulder, elbow, and forearm was developed. Orthogonal forces are measured at the arm and wrist with two multidirectional strain-gauge transducers interfaced with a laboratory computer. A software program, using lever arms and forces values, calculates the joint torques in real time according to static equilibrium equations. Surface EMG was used to complement the torque measurements.

PROGRESS—The GS of the affected upper limb of HS and the right or left side of controls was characterized during progressive maximal grip exertions on the nonaffected side. While no significant contralateral torques or EMGs were noted in controls, the magnitude of contralateral torques and EMGs in HS was graded with the severity of the motor deficit and the spasticity. GS started to increase at hand grip force thresholds corresponding approximatively to 70 percent of the MVC. The highest levels of hand grip force generated produced the most GS in HS with severe motor deficits. The most prevalent and strongest torque recorded was in elbow flexion.

PRELIMINARY RESULTS—This experimental approach has also been used successfully to characterize the electromyographic patterns of GS in HS during various tasks. Results indicate that upper limb GS are present during both grip exertions on the nonaffected side and bilateral ankle exertions but that they are more pronounced in elbow flexor muscles during grip exertions. This suggests that GS are task specific and that this specificity is probably related to different neurophysiological mechanisms. Recently, the stability of the kinematic and electromyographic patterns of upper limb GS in chronic HS was assessed. GS in elbow flexion and EMG activity of biceps brachii were found to be stable across multiple trials and sessions.

FUTURE PLANS—Electrophysiological testing of HS in conjunction with measurements taken from static dynamometry and surface electromyography will be used to study the neurophysiological mechanisms involved in GS and evaluate the effectiveness of therapeutic interventions aimed at reducing GS and their effects on the functional performance of HS.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Stability of global synkineses during hand grip in chronic stroke subjects. Boissy P, Bourbonnais D. Proceedings of the 27th Neurosciences Conference; 1997, New Orleans.

Task specificity of global synkineses in hemiparetic subjects. Boissy P et al. Proceedings of the 1997 North American Stroke Meeting; 1997, Montreal.

A static dynamometer for the measurement of shoulder and elbow torques. Boissy P et al. Proceedings of the 17th annual conference of the IEEE Engineering in Medicine and Biology Society; 1995, Montréal.

[65] QUANTIFICATION AND ASSISTANCE OF MOVEMENT DISORDERS

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PURPOSE—The objective of this study is to quantify and assist movement disorders. The diseases studied include, essential tremor, Parkinson's disease, myoclonus, Huntington's disease, and stroke. The specific problem which the research concentrates upon is twofold: 1) the impairment of handling computer interfaces such as a mouse and pen-like devices, and 2) the impairment of handwriting. The two aspects of the problem are not exclusive of each other as our approach is a synthesis of the two; that is, to develop technology for an assistive computer interface which can aid in basic computer use as well as written communication. Before any assistance can be accomplished, the movement disorders must be assessed and quantified.

METHODOLOGY—For the quantification portion of the research, target tracking tests and writing samples are utilized. Target tracking consists of a mouse/pen that is used to control a cursor on a screen to track a moving target. Accuracy, curvature, and coherence are some of the quantifications that can be obtained from such tests. For the writing samples, functional assessment is accomplished through the use of optical character recognition (OCR), the ability for a computer to recognize and read text or handwritten letters. The computer's capacity to read handwritten characters can be used to gage the functional ability of a motor impaired person. A digitizing tablet is used to take recordings for these tests.

For the assistance portion of the research, filtering algorithms designed to cancel out involuntary movements are implemented into software. A user's movements of a mouse/pen may be unsteady, but when the movements are processed by the computer, the cursor/arrow movements on the computer screen become smoother and more controllable.

PROGRESS—Large quantities of data have been obtained from control and movement-impaired people. The aforementioned quantification techniques have been used to yield revealing results.

PRELIMINARY RESULTS—A statistically valid degradation in performance has been found in the movement impaired. We have found that performance in some motor-disabled subjects may be well less than a half that of control subjects. Depending on the type of affliction, legibility may fall below 40 percent compared to a control's 80 percent and above legibility.

FUTURE PLANS—Further quantitative results are desired for a complete and comprehensive data set. The assistive algorithms developed must be tested to see if they raise performance levels of the motor disabled. Also, the potential of portable digital assistants (PDA) are being considered. PDAs that utilize OCR technology may be a powerful tool for the motor-disabled population as an all-purpose communication device.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of age and disability on target tracking with a computer mouse: accuracy and linearity. Riviere CN, Thakor NV. J Rehabil Res Dev 1996;33(1):6–15.

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On-line canceling of pathological tremor for computer interface. Hsu DS, Riviere CN, Thakor NV. Proceedings of 18th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; 1996 Nov; Amsterdam. p. 852.

StylPen: on-line adaptive canceling of pathological tremor for computer pen handwriting. Hsu DS, Huang WM, Thakor NV. Proceedings of the IEEE 22nd Annual Northeast Bioengineering Conference; 1996. p. 113–4.

[66] MEASURING FUNCTIONAL ABILITIES OF WHEELCHAIR USERS: DESIGN CRITERIA FOR WHEELCHAIR SECUREMENT

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PURPOSE—The greater independence of wheelchair travelers on public transit requires the development of user-controlled wheelchair securement systems. There is a need for a clear definition of the accessible regions for wheelchair users and of the securement tasks they can perform. The variations in user abilities also indicate the requirement for criteria to associate the functional abilities of users with operational requirements of securement systems.

METHODOLOGY—Data were collected on users who had sufficient hand and arm function to perform the range of motion (ROM) tests. The individual tasks needed to operate a securement system were identified: maneuver the wheelchair into position, grasp the rear components, attach the rear securements to the wheelchair, grasp the front components, attach the front securements to the wheelchair, and operate controls (lock, tension, release).

The performance of these tasks requires systems that are operated within the ROM, strength, and dexterity of the user. ROM was measured by placing a scale (graduated dowel) 30.5 cm behind and 91.4 cm in front of the intersection of the wheelchair seat and back, simulating the front and rear edges of the ADA specified wheelchair bay. The subject was instructed to grasp the scale as low as possible. The height of the center of the palm was recorded at each location. The distances that the individual could reach forward and overhead (while seated upright) were also measured to identify areas where vehicle-mounted controls could be located.

The hand grip and finger pinch strength was measured in a neutral sitting posture in the wheelchair using a Jamar dynamometer and pinch meter. The strength measurements were repeated at the grasp height and locations to measure the effect of reaching on strength of the user. To evaluate dexterity, three different types of karabiner hooks and one open hook were given to the subjects for attachment to a steel ring held in front of them. The degree of difficulty accomplishing these tasks was recorded.

PRELIMINARY RESULTS—Six women and 10 men (average age 37±8 yr) using 10 manual wheelchairs, 4 power wheelchairs, and 2 scooters were tested. The results indicated that user-accessible securement components should be located between 38 and 152 cm above floor level, no more than 30.5 cm inches behind or 61 cm in front of the back of the seat. The grip strength (20.4±15.4 kg) and pinch strength (5±3.6 kg) varied greatly and were substantially less than the typical values for the nondisabled population (36.3 kg grip strength, 7.25 kg pinch strength). These strength values indicated sufficient capacity that force-operated devices may be considered for securement design. Simultaneous application of force and dexterity, however, appeared to present some control difficulties. Both the operating force and geometry affected the difficulty of the attachment operation. Individuals with stronger pinch strength performed the tasks with less difficulty than those lacking finger pinch strength.

FUTURE WORK—Additional bilateral data are needed to begin to differentiate populations for whom independent securement is feasible. This information will have significant influence on securement system design for independent operation by wheelchair users.

[67] RELIABILITY OF THE UPPER BODY MUSCULOSKELETAL ASSESSMENT (UBMA) IN DIAGNOSIS OF WORK-RELATED MUSCULOSKELETAL DISORDERS (WRMD)

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Sponsor: *the Vice-President Research Grant Competition Fund, The University of Western Ontario, London, ON, Canada.*

PURPOSE—The purpose of this study was to assess the between-day reliability of an upper body musculoskeletal assessment (UBMA) of strength, range of motion, neurological symptoms, pain, and discomfort. It was developed to assess work-related musculoskeletal disorders (WRMD) in both a physician-diagnosed group of subjects and a control group.

METHODOLOGY—Twenty-five female subjects have participated to date in this ethically approved study: 15, mean age(±sd)=33(±5.25) yr were physician-diagnosed as having WRMDs. Ten subjects acted as healthy (self-described) controls, mean age=30(±2.2) yr. The WRMDs subjects were all working either part- or fulltime, at jobs that were identical or similar to their preinjury employment. The controls were all working fulltime. With the guidance of the physician on our research team, the UBMA was developed to objectively assess pain and discomfort for the neck, shoulders, elbows, and wrists bilaterally. This was done by asking subjects to actively move their limbs through complete movement ranges with the therapist/testor applying resistance at the end of range, then scoring the reported pain on a 5-point scale from 0=no pain to 4=worst pain ever experienced. Passive movement limitations were also scored for all regions as described above. Several shoulder/arm pressure points were assessed for tenderness scores, with the presence of tenderness scoring a 2. Several neurological assessments done bilaterally included those for carpal tunnel syndrome as well as sensation of the finger tips. Forearm swelling was included in the index. Discomfort was assessed for each limb in terms of duration, frequency and intensity each using a 7-point scale. A cumulative score bilaterally gave a maximal score of 190. Two graduate students (one physical therapist and one occupational therapist) collected the data after being trained by the research team physician to assess and score correctly. Subjects were tested on three separate occasions each separated by 1, but no more than 2, days. Sessions lasted 20–30 min. Data were summed for each of the right and left sides and a three-way analysis of variance (ANOVA: 2 groups×2 sides×3 occasions) was applied. Generalizability theory was utilized to calculate the reliability coefficients (RCs) to describe the intersession reliability. Maximal scores were 190 per side with a total of 380 for both sides.

PROGRESS—This study is still in progress. We intend to collect data from five more WRMD subjects.

RESULTS—Of the 15 WRMDs, 10 were affected unilaterally and 5 bilaterally; all were right-handed. In addition, 2 of the 10 controls had minimal symptoms of pain and discomfort (i.e., <10/190 on the UBMA). ANOVA results indicated no interaction effects between the 3 groups. There were also no differences between the three testing occasions. However, there was a difference between the right and left sides of the WRMDs; the right sides were significantly ($p<0.05$) different in UBMA score from the controls. All RCs were in the excellent ($RC>0.9$) range for all combinations of occasions. Therefore, between-session reliability was consistently high. Therefore, one testing occasion using the UBMA, either with the WRMDs or control groups, showed excellent reliability. This suggested that the UBMA was a good choice for upper body musculoskeletal assessment if reliability and time-efficiency are assessment requirements. Our findings also supported other work reporting that many jobs (e.g., number inputting via vieodisplay terminals) involve more movements of the dominant side, and therefore place this side more at risk for WRMD development.

FUTURE PLANS—We plan to collect data on five more WRMD subjects and redo our analyses. In addition, we plan to utilize the UBMA to assess WRMDs in heavy videodisplay terminal users at their worksites, and to ascertain the relationship between this measure and other physical and psychosocial measures over a lengthy time period, to track the success of a workplace training regime with heavy VDT users.

IV. Functional Electrical Stimulation

A. General

[68] COLONIC REHABILITATION WITH MICROSTIMULATORS AFTER SPINAL CORD INJURY

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PURPOSE—The objectives of this study include: 1) the *in vitro* evaluation of a uniquely new, fully implanted microstimulator to be used for colonic FES management after SCI; 2) the determination of the optimum number and location for the microstimulators as well as the optimum protocols necessary to induce defecation in the SCI animal; 3) the determination of the effect of the microstimulators on colonic motility and on colonic transit time; and 4) the evaluation of the biocompatibility of the microstimulators in conjunction with the histological response of the colon.

METHODOLOGY—Proposed studies include both *in vitro* and *in vivo* work. *In vitro* studies will evaluate the microstimulator's performance over time, the depth of field of the external coil to the implanted electrodes, the optimum angle of orientation between the microstimulators and the external coil, and the spread of electric field. For *in vivo* studies, one group of 18 animals will be used with each animal serving as its own control. Two survival surgeries are needed. The first to fully instrument the animal, and the second to completely contuse the spinal cord at T4. Colonic manometry and transit times will be assessed before SCI, after SCI; and after SCI with direct colonic stimulation.

PROGRESS—The University of Michigan has fabricated several prototypes and demonstrated basic functionality of these devices. Fabrication of devices for *in vivo* studies is in progress. We have started *in vitro* studies to characterize the spread of the electric field.

RESULTS—One of the most important features of the microstimulators is the glass package responsible for providing the hermetic seal as well as the feedthroughs to connect its electronics to those outside the package. This package has undergone substantial testing under accelerated conditions both in saline and DI water, and periodically tested visually by optical microscope and electrically with integrated dew point sensors for the presence of moisture. For the electrical tests, the impedance of the dew point sensors with the pads outside the package is monitored. Using the accelerated data at 85 °C and 95 °C in saline, an expected life time of 177 years at 37 °C was calculated. Based on similar studies in water, an expected life time of 485 years at 37 °C was calculated.

To characterize the functional performance of the microstimulators, methods to assess the stimulating current and electric field are required. Using an *in vitro* bath, two small surface area platinum test electrodes, and two external platinum electrodes, changes in the spread of the electric field were evaluated at various temperatures, frequencies, pulse durations, and applied currents in both DI water and saline baths. With these standard curves, we will be able to characterize the *in vitro* performance of the microstimulators.

FUTURE PLANS—We plan to assemble external coils and stimulators, fabricate additional microstimulators for *in vivo* use, and identify the optimum number and location of these fully implanted microstimulators needed *in vivo* to induce defecation.

[69] REHABILITATION OF URINARY INCONTINENCE USING STIMULATED MUSCLE FLAPS: A PILOT STUDY

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(Pilot Project #E1583PA)

PURPOSE—The artificial urinary sphincter, an inflatable balloon cuff placed around the urethra, is the most effective therapy for the restoration of urinary continence secondary to internal sphincter deficiency. It is most often used to manage urinary incontinence following radical prostatectomy for cancer. An alternative is the stimulated gracilo-myoplasty, where stimulating electrodes are placed in the gracilis muscle that is wrapped around the urethra and attached to the pubic bone laterally. This myoplasty has been named an alpha wrap. However, with this wrap, urethral mobility, ischemia, and strictures are reported complications. We evaluated modified alpha wraps to avoid these problems. Stimulated flaps were evaluated in an animal model and urethral factors were evaluted.

METHODOLOGY—Male dogs were implanted with a myoplasty stimulator. The gracilis muscle was loosely wrapped around the urethra to avoid the potential for stricture formation. The standard alpha wrap was modified with the gracilis muscle attached to the midline of the pubic bone or attached to the gracilis muscle itself. An 8-wk training period was conducted and followed by continuous stimulation for 6 weeks. Efficacy of the neosphincters was determined with urethral and leak point pressure measurements. Urethral stricture formation was assessed by dissection postmortem.

RESULTS—Seven dogs with stimulated skeletal muscle flaps have been evaluated with the modified gracilis muscle wrap around the urethra. Under anesthesia, urethral pressure increases of 10 to 150 cm H_2O were recorded with stimulation at 12 Hz and stimulating voltages from 0.5 to 3 mA. Little or no fatigue in the peak pressure response was noted during 10 min of stimulation. The modified alpha wrap with the gracilis muscle attached to itself was noted to result in urethral twisting during stimulation. Because of this high mobility it was not used further. The second wrap with the attachment of the gracilis muscle to the pubic midline resulted in little urethral movement. Urethral strictures were not observed in the four animals with this wrap. Technical problems such as detached electrodes were encountered in several of the animals. However, the stimulated gracilis neosphincter functioned well in this animal model.

FUTURE PLANS—Since these studies were initiated, clinical trials of stimulated graciloplasty have been started in several centers around the world. Our understanding is that an alpha split wrap is being used where the wrap is brought around the urethra and then through a split in the middle of the muscle before it is attached laterally to the pubic bone. This approach should minimize urethral mobility and stricture formation. We are encouraged by these clinical trials and hope to participate in the active discussion of this promising approach to management of external urethral sphincter deficiency.

[70] APPLICATION OF A 3-D REAL-TIME MOTION ANALYSIS TECHNIQUE FOR THE DEVELOPMENT OF CLOSED-LOOP CONTROL SYSTEMS FOR FES

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PURPOSE—The purpose of this study is to develop and apply a 3D real-time, TV-based motion analysis system for the control of movements induced by FES. Its applicability in the development of FES control strategies is analyzed mainly in terms of choice of the optimal kind and number of sensors and definition of stimulation controller.

METHODOLOGY—One of the key points related to the development of closed-loop FES system for movement restoration in persons with paralysis is the definition of what general control strategies to adopt. The number of kinematic and dynamic variables useful to control the stimulation activity can be very high, particularly in complex movements; therefore, the number and type of sensors are generally not known a priori and should be defined during the general system design. One possible approach is to start with a large number of sensors during the laboratory development phase and then reduce them for the clinical application of the system. In this research, we study the possibility of using a TV-based motion analysis system to perform this laboratory development phase.

A programmable stimulator driven by a PC has been interfaced with the ELITE system (a motion analysis system based on automatic recognition of passive markers performed by CCD TV cameras while infrared light is flashing the field of view), implementing a closed-loop configuration that delivers current impulse trains with the following characteristics: manually adjustable amplitude (0–150 mA), software-controlled pulse width (20–500 ms) and software-controlled pulse frequency (1–500 Hz).

In this pilot application, the movement of the knee joint was controlled with surface stimulation of the quadricep muscles, using the knee angle as the controlled variable. Three markers were positioned on hip, knee, and ankle joint and once the 3-D coordinates of each marker were detected, joint angle and angular velocity were computed in real time, and their values used by a PID controller to modulate muscle stimulation.

PRELIMINARY RESULTS—At the heaviest CPU work condition (4 active TV cameras, 3-D graphic representation on 3 planes, and contemporary data saving on HD), up to 12 markers seen by each TV camera were successfully managed at the maximal system sample rate of 100 Hz. This performance seems suitable for many FES application. Moreover, due to the real-time algorithm implementation, a progressive decrease of sampling rate is the only consequence of processing a higher marker number. Concerning the experiment on knee movement control, the general performance was comparable to the results previously obtained with a traditional electrogoniometer, with several advantages: absence of any external devices on the subject's body, higher system accuracy, less artifact due to skin movement, and the ease in changing the position and configuration of the markers. The main limitation of this approach, its restricted working volume, makes it suitable for local movements (standing up, sitting down, walking on treadmill, and upper limb movements).

FUTURE PLANS—Experiments with a more comprehensive approach, exploiting the possibilities provided by a motion analysis system based on passive marker recognition will be performed.

[71] MICROSTIMULATION OF THE LUMBOSACRAL SPINAL CORD: MAPPING

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PURPOSE—The objective of this project is to investigate the feasibility of genitourinary and motor system neural prosthetics based on intraspinal microstimulation.

PROGRESS—Expression of the immediate early gene, c-Fos was used to map the location of spinal neurons involved in control of genitourinary function. Male cats were anesthetized with alpha-chloralose and received 1 of 3 stimulus protocols: electrical stimulation (2 hr, 1 s ON/1 s OFF, 20 Hz) of the pelvic nerve (n=2) or the pudendal nerve (n=2), or a 2-hr period of isometric micturition (n=2) induced by ligating the proximal urethra and infusing saline into the bladder (1 ml/min) until spontaneous periodic bladder contractions occurred. Stimulation with each protocol resulted in a larger number of cells expressing Fos-like immunoreactivity (FLI) than in operated but unstimulated controls, which exhibited few, scattered Fos-positive cells. In stimulated animals, nuclei exhibiting FLI were found bilaterally in S1-S3 and were localized to the lateral portion of the superficial dorsal horn (laminae I and II), the neck of the dorsal horn (laminae V and VI), and within small cells in the dorsal commissural nucleus. Fewer Fos immunoreactive nuclei were observed in the medial portion of the superficial dorsal horn and FLI was rarely observed in ventral horn neurons. In animals receiving electrical stimulation of the pelvic nerve or undergoing isometric micturition, FLI was also present in larger cells within the intermediolateral cell column of S2-S3. The results of these studies identify spinal neurons involved in control of the genitourinary system, and provide regions to target with microstimulation.

RESULTS—The motor responses generated at the knee joint were mapped by intraspinal microstimulation. Adult cats were anesthetized with alpha-chlorolose and the isometric torque generated was recorded in response to 1 s trains of 20 Hz 100 μs biphasic current pulses (10–150 μA) applied along vertical dorsal-to-ventral penetrations made between spinal segments L7 and L4. Electrode locations in the ventral horn generated the largest torques (averaged over 1 s stimulus interval): 5–15 N-cm extension, 5–10 N-cm flexion. There was mediolateral segregation of the torque responses in a rostrocaudal plane. Medial electrode placements generated primarily flexion torques and lateral electrode placements generated primarily extension torques. Large flexion torques were also generated by microstimulation along a vertical band in the medial dorsal horn, paralleling the dorsal root entry zone. These results indicate that microstimulation of the spinal cord allows selective activation of knee flexors and extensors by both direct and indirect activation of spinal motoneurons, and that the magnitudes of the evoked torques are small relative to those evoked by ventral root or peripheral nerve stimulation.

Urethral pressure profiles, anatomical reconstructions, and electrical stimulation of the pudendal nerve were used to document the anatomy of the feline periurethral musculature and determine the neural pathways that mediate the effects of intraspinal microstimulation. From the distal part of the prostate, striated muscle increased progressively and became predominant in the postprostatic urethra. Rapid spontaneous fluctuations and higher baseline pressures were recorded distal to the prostate, but were absent in the preprostatic urethra. These pressures resulted from the basal tone in the urethralis and external urethral sphincter (EUS) muscles and were abolished by Flaxedil. At the level of the EUS the pressure measured along the ventral side of the urethra was higher than along the dorsal side. This correlated with a ventral bias in the size of the EUS. Pressure increases elicited by pudendal nerve stimulation were detected in the postprostatic urethra and bulbourethra, regions where periurethral striated muscle was identified.

RECENT PUBLICATIONS FROM THIS RESEARCH

Isometric knee torque generated by microstimulation of the lumbar spinal cord. Grill WM, Wang B, Bhadra N. Proceedings, International Functional Electrical Stimulation Society (IFESS) Second Annual Conference; 1997 Aug 16-20, Burnaby, BC.

Mapping knee torques evoked by intraspinal microstimulation. Grill WM, Wang B. Proceedings of the 19th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; 1997 Oct 29-Nov 2, Chicago, IL.

Urethral pressure responses to stimulation of afferent and efferent neurons in the pudendal nerve and sacral spinal cord of male cats. Wang B, Grill WM, Bhadra N. Proceedings, International Functional Electrical Stimulation Society (IFESS) Second Annual Conference; 1997 Aug 16-20, Burnaby, BC.

[72] THE DYNAMIC MODEL OF SKELETAL MUSCLES AND JOINTS FOR FES APPLICATIONS

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PURPOSE—Discerning the correct response model of a single skeletal muscle has been a long-standing problem, because only unphysiological control inputs (firing rate or reverse recruitment) could be used, or alternate analogue models preassumed the interaction mode of firing rate and recruitment, which were unknown until recently. The model is needed for the design of advanced FES systems.

METHODOLOGY—We tested the soleus (slow twitch) and M. gastroc (fast twitch) under several physiological control strategies with the aid of our newly developed stimulation system that recruits motor units in an orderly fashion.

PROGRESS—Additional work has identified the frequency response of nine different muscles in the hind limb of the cat. The impact of muscle/tendon ratio, mass, pennation, and twitch properties varied the model poles from 1.6 to 2.8 Hz. Recent studies focused on load moving contractions and on the effect of the joints in various configurations. Muscle architecture and its predominant fiber composition seem to be the primary variable in determining its dynamics, whereas the tendon is a secondary factor. Recent work identified the dynamic model of antagonistic muscle pair acting on the ankle joint of the cat.

RESULTS—The frequency response model consisted of a second-order system with double poles at 1.8 Hz. This was independent of the control strategy used, the predominant muscle fiber type, or the force perturbation level. A pure time delay differentiated the models for fast and slow twitch muscles being 11 ms and 16 ms, respectively. Firing rate control input was reaffirmed to result in a nonlinear model as previously described in the literature.

RECENT PUBLICATIONS FROM THIS RESEARCH

The influence of antagonist muscle control strategies on isometric frequency response of cats ankle joint. Goodwin A, Zhou B-H, Baratta RV, Solomonow M, Keegan A. IEEE Trans Biomed Eng 1997;44:634–9.

[73] THE USE OF EMG AS FORCE FEEDBACK IN CLOSED-LOOP ELECTRICAL STIMULATION SYSTEMS

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PURPOSE—Force feedback is necessary regulation of a stimulated muscle force output is anticipated. Since implantation of force sensors requires trauma to the tendon, the EMG was considered, tested, and evaluated as a parameter-representing force in a closed-loop paradigm.

METHODOLOGY—The EMG was found to follow the isometric force rather faithfully as long as fatigue did not set in the muscle. In order to prevent muscle abuse and possible damage due to prolonged and frequent fatigue, a parallel feedback/fatigue detector has been implemented. The role of such a circuit is to function as a "fatigue fuse," terminating contractions if excessive fatigue is detected.

PROGRESS—The EMG-force relationship was investigated in order to delineate the effects of changing muscle length, and moment arm about the joint's center of rotation, in order to extend the concept to nonisometric contractions in a moving limb. It was shown that various factors influence the EMG-force relations, and that a multivariant model should be constructed to provide accuracy to the feedback loop. Recent evidence delineate changes in force and EMG in different contraction types and after skill acquisition.

RECENT PUBLICATIONS FROM THIS RESEARCH

Motor unit recruitment strategy of antagonist muscle pair during linearly increasing contractions. Bernardi M, Solomonow M, Baratta RV. EMG Clin Neurophysiol 1997;37:3–12.

Motor unit recruitment strategy changes with skill acquisition. Bernardi M, Solomonow M, Nguyen G, Smith A, Baratta RV. Eur J Appl Physiol 1996;74:52–9.

[74] DETERMINATION OF THE OPTIMAL MOTOR UNIT RECRUITMENT STRATEGY FOR APPLICATION IN A HIGH PERFORMANCE FES SYSTEM FOR QUADRAPLEGICS

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PURPOSE—The objective of this investigation was to determine the optimal motor unit control strategy that should be used in electrical stimulation of the upper limb and hand of persons with quadraplegia in order to provide them with most accurate control of force increase and decrease, a part of a long-term objective of designing a high-performance FES system.

METHODOLOGY—A group of controls were trained to track a 3-s long linear increase in force of their elbow flexors in isometric condition while recording the EMG of the flexors (agonist) and extensor (antagonist) muscles. The power spectra frequency of the EMG signal was obtained and its median frequency (MF) calculated. Measurements were made in the beginning of a 6-wk-long training program, and every 2 wks thereafter. The MF being representative of the conduction velocity of the muscles action potentials, indicated the increase or decrease in motor unit recruitment.

It was shown that at the end of the 6-wk program, the subjects tracking capability become highly accurate while their motor unit recruitment strategy increased from 0–65 percent of the maximal muscle force to 0–90 percent of the maximal muscle force.

IMPLICATIONS—A FES system when applied to rehabilitation of arm and hand functions of persons with quadraplegia, where high precision of force control is required, should employ orderly stimulation of motor units over the full range of the available force in order to provide fine increments of force increase.

RECENT PUBLICATIONS FROM THIS RESEARCH

Motor unit recruitment strategy of antagonist muscle pair during linearly increasing contraction. Bernardi M, Solomonow M, Baratta RV. EMG Clin Neurophysiol 1997;37:3–12.

Motor unit recruitment strategy changes with skill acquisition. Bernardi M, Solomonow M, Nguyen G, Smith A, Baratta RV. Eur J Appl Physiol 1996;74:52–9.

[75] EFFECT OF INGESTED SODIUM BICARBONATE ON MUSCLE FORCE, FATIGUE, AND RECOVERY

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Sponsor: *The Segal Foundation, Israel*

PURPOSE—We seek to evaluate the effect of ingestion of $NaHCO_3$ on muscle progressive fatigue as induced by FES and on muscle recovery after intensive cycling exercise.

METHODOLOGY—The influence of acute ingestion of $NaHCO_3$ on fatigue and recovery of the quadriceps femoris muscle following exercise was studied on six nonimpaired male controls. A bicycle ergometer was used for exercising under three loading conditions: A) load corresponding to $\mathring{V}_2$max; B) load A+17 percent; C) load B but performed 1 hour after acute ingestion of $NaHCO_3$.

The relationship between short-term physical effort performed during cycling and the resulting decrease in blood pH level due to lactic acid accumulation is well documented. End-tidal CO_2 pressure ($PETCO_2$) was used in this study to indirectly reflect humoral acid-base changes due to bicarbonate decrease.

Functional electrical stimulation (FES) was applied to provoke isometric contraction of the quadriceps femoris. The resulting knee torque was monitored during fatigue (2 min chronic FES) and recovery (10 sec FES every 10 min, for 40 min). This procedure provided standardized testing protocols and ensure reproducibility of the testing conditions.

RESULTS—The results obtained indicate that during supramaximal load (test B) a significant decrease in $PETCO_2$ resulted in comparison to load $\mathring{V}_2$max (test A), reflecting a decrease in bicarbonate buffer formation. However, when the supramaximal load was combined with acute ingestion of bicarbonate (test C), a significantly higher $PETCO_2$ level resulted, indicating an increased CO_2 accumulation in the blood and a more effective bicarbonate buffer activity. Quadriceps torques were found higher in the presence of $NAHCO_3$ ($p<0.05$): With $NaHCO_3$ the peak, residual and recover (after 40 min) normalized torques (mean±SD) were 0.68(0.05), 0.58(0.05) and 0.73(0.05), respectively; without $NaHCO_3$ the values were 0.45(0.04), 0.30(0.06) and 0.63(0.06), respectively. The increased torques obtained following acute ingestion of sodium bicarbonate indicate the possible existence of improved non-oxidative glycolysis in isometric contraction, resulting in reduced fatigue and enhanced recovery.

FUTURE PLANS—It is planned to study the effect of ingested $NaHCO_3$ on paraplegic subjects who use FES functionally for reducing their muscle fatigue and enhancing recovery.

RECENT PUBLICATIONS FROM THIS RESEARCH

Verbitsky O, Mizrahi J, Levin M, Isakov E. Effect of ingested sodium bicarbonate on muscle force, fatigue and recovery. J Appl Physiol 1997. In press.

[76] DYNAMICS OF FORCE RECRUITMENT OF THE PARALYZED MUSCLE BY FES

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Sponsor: *The Segal Foundation, Israel*

PURPOSE—We seek to develop an analytical model that allows to calculate the current distribution within a stimulated muscle and obtain the isometric recruitment curve (IRC).

METHODOLOGY—A general model of the electric field within a layered medium with arbitrary placement of surface or intramuscular electrodes is developed. First, by using the method of separation of variables, we obtain the solution in an integral form. We then convert this solution into an infinite (hyper-geometric) image series representation. This leads us to the same solution that would have been obtained had the image technique been applied directly. The image series expansion is used to obtain numerical results, which are compared to results obtained by numerical integration.

The next step is to obtain the interaction between the electric field and the excitable cell, by examining the current density along the fibers and by comparing it to the excitation threshold. In this way a predicted IRC is obtained and used for comparison with experimentally obtained data. The advantage of the analytical approach developed is its ease of application for the rapid and accurate determination of the electric field in heterogeneous medium resulting form FES.

Two particular models are solved: transcutaneous and percutaneous stimulation. The first stage is determination of the current density distribution within the muscle slice for both models. The second stage counts the elements within the active slice that escape the activation threshold for various values of input current. Whenever the longitudinal component of the current density exceeds the excitation threshold, contraction is assumed to take place and force is generated. The average force produced is calculated as the ratio of the number of fibers in the muscle.

RESULTS—Sensitivity of the model to different parameters such as tissues reflection coefficients, activation threshold, and fiber length was verified. The resulting model demonstrated characteristic features which were similar to experimentally obtained data. The model also quantitatively indicated the difference between surface and implanted electrode recruitment.

The intramuscular IRC gave a higher slope than that of the surface stimulation IRC, due to the higher current density values resulting when intramuscular stimulation is used. An additional feature of the IRC in this case was the absence of an initial dead zone region, possibly because of the presence of singular values of the current density near the stimulation electrodes, due to the point source representation of stimulation.

To overcome the problem of singularity, we plot circular equipotential lines around the point sources. The radii were chosen to be less than the skin layer thickness.

The current density distribution obtained in the surface stimulation model was found largely nonuniform. This may lead to fast fatiguing of the fibers adjacent to the stimulating electrodes. The intramuscular stimulation model demonstrated a more uniform current density profile with depth. Nevertheless, it had a region with a relatively low current density midway between the stimulation electrodes. Decreasing the interelectrode distance or using additional stimulation electrodes can help in making the current density more evenly distributed.

FUTURE PLANS—The point-source solution (green-function) of the potential problem with stratified media will be used to calculate the potential distribution due to electrodes with finite dimensions. The numerical results will be obtained by using infinite image series expansions. The effect of multi-array electrode configurations on the spatial distribution of the electric field will also be investigated.

[77] THE EFFECTS OF TRAINING BY FES ON MUSCLE GEOMETRY AND FORCE

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Sponsor: *The Segal Foundation, Israel*

PURPOSE—This study was designed to quantify the cumulative effects of training by FES on the hypertrophy and strengthening of paralyzed muscles. In previous studies, the changes of geometrical properties of the muscles over the training period were assessed by obtaining axial images from the region of the mid-thigh. Those images were acquired by using either MR or CT imaging techniques. However, imaging of the mid-thigh region is not sufficient for evaluation when one focuses on the conditioning of a specific muscle, since muscle bellies of the thigh extensors and flexors are not aligned. In this study we use contiguous axial and sagittal images of the whole thigh and a polynomial curve-fitting technique to acquire the geometry of each of the knee extensors. Estimated geometrical properties include maximal cross-sectional areas (CSA) and volumes of the thigh extensors, which are used to quantify the cumulative effects of training by FES on hypertrophy of these muscles. The effect of training is also measured by means of the torque applied by the muscle.

METHODOLOGY—Data for the MRI study are collected on a whole body MR imager. Standard soft tissue MRI protocols (T1-weighted) are used to generate a series of axial 15 mm slices with 6 mm interslice gap and sagittal 10 mm slices with 4 mm gap contiguous cross-sectional within a field of view of 500 by 500 mm. The images are analyzed using a built-in ''irregular region of interest (IRROI)'' area measure program of the imager. A series of contiguous axial images of the thigh are acquired from the plane of the greater trochanter to the plane of the condyle of the femur. In calculating the CSA of muscles of the GVS, the cursor is used to exclude neurovascular structures, accumulations of fat, and fibrous tissue bundles that are clearly delineated from the muscle groups. The relative orientation between the longitudinal axes of the thigh muscle and the image frame is estimated and enables evaluation of the CSA of the muscles perpendicular to their longitudinal axis. The areas of the thigh muscle include: rectus femoris (RF), vastus lateralis (VL), and vastus medialis (VM). They are curve-fitted by using the least squares (LSQ) polynomial regression method, to interpolate the muscle CSA versus the distance x from the proximal aponeurosis.

Torque measurements are taken from the right thighs of both subjects during the supra-maximal contraction sessions. Torques are curve-fitted using a tri-exponential analytical function, and the force in the quadriceps is calculated.

RESULTS—The results show a significant ($p=0.024$) increase of the CSA at the muscle belly of the right RF muscle. It should be remembered that the right RF is subjected to both isotonic and isometric activation. These findings support the hypothesis that supra-maximal, isometric, activation may enhance strengthening of the trained muscle.

The changes in the muscle's force production capacity consist of a general increase in the peak of the torque. These changes are accompanied by a significant enhancement of the CSA of the right RF. This may indicate that in the training time followed-up in this study (12 wks), the main muscle change is a general increase in cross-sectional area. It cannot be concluded, however, whether this change is the result of an increase in fiber diameter, number of fibers, or any combination of both.

[78] MODELING OF FATIGUE AND RECOVERY IN FES TO ALLOW PREDICTION OF MUSCLE FORCE

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PURPOSE—We are working to develop a musculotendon model of a FES activated paralyzed muscle to allow prediction of muscle force during interrupted stimulation, in which processes of fatigue and recovery take place in sequence.

METHODOLOGY—The muscle is modeled in terms of five elements, including muscle mass and tendon, connected in series with three parallel elements, two of which are passive, representing elasticity and viscosity of the parallel-arranged muscle fibers. The third parallel component is the contractile element (CE) that represents the activated fibers.

Myoelectric (M-wave) and metabolic data are used to evaluate the neural excitation and metabolic history of the activated muscle, from which the activation dynamics and the fatigue function of the contractile mechanism are derived, respectively. The active state of the muscle fibers defines the fraction of regulatory sites on troponin with calcium bound, and is evaluated by substituting the neural excitation into an activation dynamics model.

The measured metabolic parameters include Pcr, Pi, pH and H_2PO_4. During interrupted stimulation, fatigue and recovery occur alternately. The histories of the above-mentioned metabolites must therefore be expressed in terms of two time-dependent metabolic functions, one for fatigue and one for recovery. Force-metabolite relations are predicted by curve-fitting of the force output during primary fatigue, measured simultaneously with the phosphometabolites. The fatigue experiments of supramaximally and transcutaneously stimulated quadriceps muscles of paraplegic subjects are made isometrically. Each test includes two contractions, one of 180 sec and one of 100 sec, separated by rest periods of 1, 3, 6, 12, 15, and 18 min. The knee joint torque and the surface EMG (M-wave signal) of the quadriceps muscles are recorded simultaneously. The time courses of the knee joint torque and of the M-wave peak-to-peak amplitude are curve-fitted, using a tri-exponential analytical function. This allows the consistent definition and calculation of the maxima and slopes in the force and EMG curves.

RESULTS—The build-up phase of the force curve is predicted from the EMG-signal The decaying phase of the curve is predicted by one of the phosphometabolites, depending on the duration of the rest period between the contractions. The results obtained present different prediction capacities of the model, in accordance with the selected input metabolite. For a short period of rest (1 min), Pi provides a good agreement between predicted and measured force, as opposed to H_2PO_4 and pH. After 6 min of rest, good predictability is obtained when using H_2PO_4. Finally for a long period of rest (15 min), the optimal prediction is obtained by using the pH history. The model results indicate that in post-recovery fatigue, the above-mentioned metabolites provide reliable predictors of the muscle force capacity after different rest periods. The force/recovery kinetics may, however, involve at least two time scales, each governed by a different metabolic process.

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B. Upper Limb Applications

[79] RESTORATION OF FOREARM AND ELBOW FUNCTIONS BY FNS

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PURPOSE—The purpose of this project is to restore forearm and elbow control with hand grasp for people with cervical level SCI. Our objective is to increase the range and type of functions they can perform by stimulating paralyzed pronator quadratus and triceps in addition to muscles providing hand grasp and release. We hypothesize that augmenting the hand-grasp neuroprosthesis will give individuals with C5 and C6 SCI the ability to grasp and move objects over a greater range of spatial locations and orientations, and will improve movement quality.

METHODOLOGY—Elbow and forearm stimulation is integrated with the VA/CWRU hand-grasp neuroprosthesis. The triceps is stimulated to provide elbow extension. Stimulation is adjusted to overcome gravity and can be controlled via an accelerometer mounted on the upper arm, a user-initiated stimulation with a switch on the wheelchair, or a constant triceps stimulation whenever the neuroprosthesis is active.

Elbow angle is controlled by the subject voluntarily contracting the biceps to counteract elbow extension. Forearm rotation is provided by stimulating the pronator quadratus at a constant level, whenever the hand-grasp neuroprosthesis is active. Supination/pronation angle is controlled by voluntary supination to counteract pronation. Thus, the additional functions do not require additional command signals unrelated to the desired function.

Forearm and elbow functions are evaluated in terms of basic mechanical capabilities, ability to use the restored function to achieve stable postures and produce smooth movements, and ability to perform common activities of daily living that require picking up and placing objects over a wide range of locations and orientations.

PROGRESS—This is the final year of this project. Eight neuroprostheses combining hand grasp with proximal arm control were implemented in six individuals. All neuroprostheses were used on a regular basis outside of the laboratory and were implemented with either a fully implanted stimulator and electrodes, a combination of an implanted stimulator for hand grasp and percutaneous electrodes for proximal function, or percutaneous electrodes only. Four individuals (three unilateral, one bilateral) received elbow systems. Three (two unilateral, one bilateral) received forearm systems. One individual received both elbow and forearm control in one arm.

We designed a series of tests to measure the mechanical properties at the joints with restored function (joint moment, range of motion, and dynamic stiffness); to assess the upper extremity functional workspace; and to assess improvements in functional performance.

RESULTS—Stimulating the pronator or triceps typically restored strength to grade four. Each person was able to grade the joint movement over the full range of motion by contracting the voluntarily controlled antagonist. Joint stiffness was increased by stimulation of the antagonist, which should provide better postural stability. Elbow extension increased the controllable workspace, both by increasing the range of locations and orientations where objects could be acquired and by reducing the time required to grasp the object. This is consistent with the need for elbow extension to counteract gravity and provide a stable joint. Functionally, elbow extension greatly improved task performance. However, the benefits of pronation were less dramatic. Pronation may be more important to restore in people with weaker residual function, and it may be necessary to employ more sensitive evaluation measures to elucidate the significance of pronation in these individuals.

FUTURE PLANS—We will complete the evaluation of the restored proximal function in all individuals who have received the neuroprostheses.

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Restoration of pronosupination control by FNS in tetraplegia: experimental and biomechanical evaluation of feasibility. Lemay MA, Crago PE, Keith MW. J Biomech 1996;29:435–42.

[80] FUNCTIONAL NEUROMUSCULAR SYSTEMS FOR UPPER EXTREMITY CONTROL

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PURPOSE—The research goal is to deploy and quantitatively evaluate advanced implantable functional neuromuscular stimulation systems to restore hand grasp and release in C5 and C6 quadriplegic individuals.

METHODOLOGY—The FDA has recently approved the marketing of 8-channel implantable neuroprostheses to provide grasp and release for individuals with C5 and C6 quadriplegia. The focus of this project is the clinical implementation and evaluation of a second generation implantable hand/arm system. This new system consists of a 10-channel implant stimulator-telemeter, an implanted joint angle transducer (IJAT), and 10 epimysial or intramuscular electrodes. The IJAT is placed in the wrist and uses a magnet and three Hall-effect magnetic field sensors to sense wrist angle. The magnet is inserted into the lunate. The Hall-effect sensors are inserted into the radius near the articular surface of the bone. Sensor outputs are relayed to the stimulator-telemeter device and transmitted out of the body through a radio frequency link using reflectance modulation.

The motor functions provided by the system are: multiple hand grasp patterns, including fine grasp controlled by finger intrinsic activation; elbow extension through a combination of electrical stimulation of the triceps and tendon transfers of the voluntarily controlled posterior head of the deltoid; and forearm supination/pronation through stimulation of the pronator quadratus. Elbow and forearm movement is controlled by voluntary activation of the antagonists.

Participants undergo at least 1 mo of surface stimulation prior to surgery. Implantation surgery is followed by 3 wks of casting, and then a period of muscle conditioning using the implant stimulator. A 2- to 3-wk rehabilitation training and evaluation period is used to complete the initial setup of the grasp and control parameters, train the individual in the use of the neuroprosthesis, and evaluate the function provided.

PROGRESS—The implementation of the system has proceeded in two stages. Three persons with C6 level SCI have undergone the first stage involving implantation of the stimulator-telemeter device and 10 electrodes. All three have two intramuscular electrodes placed in the finger intrinsic muscles to provide MP flexion and IP extension; two have a single electrode in the triceps for elbow extension; and one has an electrode implanted in the pronator quadratus for forearm pronation. During this stage, control of the neuroprosthesis is provided by an externally mounted wrist angle transducer.

The second stage involves the implantation of the IJAT and connection to the previously implanted stimulator-telemeter. One subject has completed this stage and the sensor is operational.

RESULTS—All three implant recipients are daily users of the neuroprosthesis, performing various functional tasks, including eating, drinking, writing, and grooming. Two have full elbow extension with triceps stimulation that allows them to perform reaching activities.

The implantation of the IJAT was successful. The output of the three sensors provide an adequate signal for the control of grasp opening and closing. No reduction in wrist range of motion has been detected post-surgery.

FUTURE PLANS—Two subjects will progress to implantation of the IJAT. In September 1997, the entire system will be implanted for the first time in a single stage.

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[81] DISCOMFORT ASSOCIATED WITH PERCUTANEOUS AND SURFACE NEUROMUSCULAR STIMULATION DURING TREATMENT OF POST-STROKE SHOULDER SUBLUXATION

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Sponsor: *National Institute on Disability and Rehabilitation Research, US Department of Education; National Institute on Aging, National Institutes of Health; Department of Veterans Affairs FES Center*

PURPOSE—Surface neuromuscular stimulation has been shown to decrease post-stroke shoulder subluxation and associated pain. However, the pain and the labor-intensive nature of surface stimulation limit the clinical implementation of this promising technique. Percutaneous intramuscular stimulation may be better tolerated since pain fibers on the skin are not stimulated. The purpose of this study is to compare the level of pain or discomfort associated with percutaneous and surface neuromuscular stimulation of the shoulder girdle muscles.

METHODOLOGY—The supraspinatus and the posterior deltoid muscles of 10 stroke survivors with shoulder subluxation and intact sensation were stimulated with percutaneous and surface electrodes. Percutaneous electrodes were of helical configuration wound from FEP-Teflon insulated, multistranded, type 316L stainless steel wires with a stimulation surface of 10 mm^2. A balanced biphasic, cathodic-first, capacitively coupled, constant-current pulse was applied. The amplitude and frequency were maintained at 20 mA and 16 Hz, respectively. Intensity of stimulation was modulated by varying the pulse width from 0 to 200 μs. Reusable gel electrodes (31.7 mm) were used for surface stimulation. A symmetric biphasic waveform with pulse duration of 300 µs was applied at 25 Hz. Intensity of stimulation was modulated by varying the pulse amplitude from 0 to 100 mA. All pain measurements were taken with a 10-cm visual analogue scale and the Pain Rating Index. Three pairs of percutaneous and surface electrode induced pain measurements were taken per subject. Subjects were asked to describe the nature of their pain with each electrode type, and to choose the electrode type they prefer for long-term stimulation. All data were analyzed with parametric and nonparametric-paired statistics.

RESULTS—Surface neuromuscular stimulation caused significantly greater discomfort than percutaneous stimulation on both the visual analogue scale (p=0.004) and the Pain Rating Index (p=0.02). Subjects described the discomfort associated with percutaneous stimulation as "aches, dull pain, muscle cramps, or none." Pain from surface stimulation was described as "sharp, burning, or pins and needles." Nine out of 10 subjects preferred percutaneous over surface stimulation for long-term stimulation.

IMPLICATIONS—Percutaneous stimulation is well tolerated by stroke survivors. This technique may facilitate the clinical implementation of neuromuscular stimulation for the treatment of post-stroke shoulder subluxation.

[82] PERCUTANEOUS NEUROMUSCULAR STIMULATION FOR THE TREATMENT OF SHOULDER SUBLUXATION IN HEMIPLEGIA

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PURPOSE—Surface stimulations of the posterior deltoid and supraspinatus have been shown to reduce post-stroke shoulder subluxation and associated complications. However, cutaneous pain and associated poor compliance, poor muscle specificity, and the labor-intensive task of consistently localizing motor points limit the practical application of surface stimulation for shoulder subluxation. The purpose of this case study is to assess the effectiveness of percutaneous neuromuscular stimulation in reducing shoulder subluxation and the associated pain.

METHODOLOGY—The supraspinatus and the posterior deltoid muscles of chronic stroke survivors were implanted with percutaneous intramuscular electrodes. The amplitude and frequency were maintained at 20 mA and 16 Hz, respectively. Intensity of stimulation was adjusted to clinical reduction of the subluxation by adjusting the pulse duration between 10–200 µs. Duty cycle of 4 s ramp-up phase, 10 s on phase, 4 s ramp-down phase, and 8 s off phase was employed with total stimulation time of 6 hrs per day. The degree of shoulder subluxation and pain were assessed at pre-treatment, post-treatment and at 3 mo post-treatment. Outcome measures included the degree of shoulder subluxation (radiographs), pain free shoulder lateral range of motion, and the Brief Pain Inventory.

RESULTS—Seven of the anticipated 10 subjects have completed the treatment phase. Three have completed the entire protocol, and four are in the follow-up phase. At the end of the treatment phase, five subjects exhibited reduction in the degree of subluxation and six exhibited decrease in the shoulder pain. Of the three who completed the entire protocol, two maintained shoulder reduction compared to baseline and one showed no change from baseline. However, all three had less shoulder pain at 3 mo follow-up compared to baseline.

IMPLICATIONS—The preliminary data suggest that percutaneous neuromuscular stimulation is effective in treating post-stroke shoulder subluxation and the associated pain.

[83] RESTORATION OF SHOULDER MOVEMENT IN C5 TETRAPLEGIA

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PURPOSE—This study will implement, evaluate, and optimize a neuroprosthesis based on functional neuromuscular stimulation (FNS) to restore shoulder function to spinal cord injured individuals with C5 tetraplegia. Such persons retain little or no voluntary control over motions that act to move the upper arm toward the midline, due primarily to paralysis of the pectoralis major (PM) and latissimus dorsi (LD) muscles. This loss of control significantly reduces the range of motion of the hand, excluding an important workspace volume near the midline, and prevents arm stabilization in the natural adducted postures used in many tasks like eating and writing. Restoration of these functions would improve independence in daily activities, improving quality of life and reducing attendant care costs.

METHODOLOGY—Percutaneus electrodes are implanted into the PM and LD muscles. Controlled stimulation of these muscles provides shoulder function in horizontal flexion, adduction, and internal rotation in individuals with C5 tetraplegia. The stimulated contractions restore the lost motions, while retained voluntary control of antagonistic muscles is used to overcome the stimulated contractions and achieve intermediate positions. Performance is evaluated by quantifying the expansion of the workspace volume accessible to the hand, the increased postural stability within this workspace, and the increase in speed and accuracy of arm movements.

Methods for improving control of the partially paralyzed shoulder are also under development. Shoulder stiffness properties are used to identify deficits in postural stability and to suggest changes in stimulation patterns to correct the deficits. The feasibility of using electromyographic (EMG) recordings from voluntarily controlled shoulder muscles to modulate stimulation of the paralyzed muscles is also being investigated for improving movement performance, preventing fatigue, and compensating for changes in contraction strength in different shoulder positions.

PROGRESS—We have found FNS of the PM and LD muscles in individuals with C5 tetraplegia produces contractions adequate to move the arm and stabilize it during posture. Retained voluntary control can overcome the stimulated contractions when desired. Surface EMG recordings from shoulder muscles with retained voluntary control can be used to accurately estimate elbow angle as well as three shoulder angles (elevation, horizontal flexion, and internal rotation).

RESULTS—The PM and LD muscles of two individuals with C5 tetraplegia have been implanted with percutaneous stimulation electrodes, with both arms implanted in one of these subjects. FNS-mediated exercise has been found to significantly increase the strength of both of these muscles. The strength is dependent on the position of the arm, with both horizontal flexion and adduction being stronger with the arm elevated above horizontal. However, the moments produced were strong enough (5–10 Nm) in all arm positions to move the arm in the desired directions.

We are developing a method for the user control of the additional shoulder functions and have found that elbow joint angle and three shoulder angles can be predicted to within 10–15° using surface EMG recordings of muscles under voluntary control (anterior, middle, and posterior deltoid, biceps, upper, and middle trapezius). An artificial neural network predicts the elbow and shoulder movements using EMG and angle measurements obtained during voluntary movements. This network is capable of accurately predicting the joint angles during single joint movements, reaching movements, and complex drawing movements.

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[84] HAND NEUROPROSTHESIS IN CHRONIC HEMIPLEGIA

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PURPOSE—A fully implantable hand neuroprosthesis system enhances the ADL function of persons with C5-C6 tetraplegia. However, it is unclear whether a similar system will be beneficial to stroke survivors with a nonfunctioning hand. The purpose of this study is to assess the functional benefit of a percutaneous hand neuroprosthesis system in chronic hemiplegia.

METHODOLOGY—Six chronic stroke survivors with volitional control of the hemiparetic shoulder and elbow, but with nonfunctioning hand were implanted with percutaneous intramuscular electrodes into various muscles of the hand and forearm. All subjects underwent a conditioning exercise protocol consisting of cycles of hand opening and closing for approximately 2 hrs per day. Various control methods are under investigation, including foot pedals, hand operated potentiometers, shoulder and wrist angle transducers, and EMG-controllers.

RESULTS—Selective stimulation with good contraction of each of the implanted muscles was achieved with minimal spillover to adjacent muscles. The degree of discomfort varied with specific muscles, but was minimized by adjusting stimulation parameters, while maintaining the desired range of motion and torque. All subjects experienced modest gain in the upper-extremity Fugl-Meyer scores during conditioning, but the motor scores of all subjects subsequently plateaued. Electrical stimulation opened and closed the hand adequately, even in the midst of strong flexor tone. However, success in controlling the system was limited to those with normal shoulder and elbow movement and volitional wrist control. A wrist angle transducer allowed these subjects to open and close the hand volitionally. An EMG-controlled stimulator is presently under investigation to enhance the wrist control strategy as well to augment proximal arm control.

IMPLICATIONS—Results to date indicate that percutaneous neuromuscular stimulation can open and close the hand. However, the problem of unstable proximal arm control and control strategy paradigm remain to be elucidated.

[85] EFFICACY OF NEUROMUSCULAR STIMULATION IN ENHANCING THE UPPER EXTREMITY MOTOR AND FUNCTIONAL RECOVERY OF ACUTE STROKE SURVIVORS.

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PURPOSE—Surface neuromuscular stimulation has been shown to enhance the motor recovery of stroke survivors. However, controlled studies have not demonstrated that electrical stimulation enhances functional recovery. The purpose of this double blind, placebo controlled, randomized trial is to assess the efficacy of surface neuromuscular stimulation in enhancing the upper extremity motor and functional recovery of acute stroke survivors.

METHODOLOGY—Stroke survivors admitted to an inpatient stroke rehabilitation program within 6 wks of their acute stroke were randomly assigned to treatment or placebo group. Motor status at entry was limited to synergy movements or if isolated movement was present, wrist extension muscle grade was less than antigravity strength. The treatment group received 1 hr of surface electrical stimulation to the finger and wrist extensors per day, 5 times a week for 3 wks. Stimulation parameters were adjusted for patient comfort and full wrist extension range of motion. The control group received electrical stimulation away from the motor point of the wrist and finger extensors, with intensity adjusted to just above sensory threshold. Outcomes were assessed at end of treatment, 1 mo post-treatment and at 3 mo post-treatment with the self care component of the Functional Independence Measure and the upper extremity component of the Fugl-Meyer Motor Assessment in a blinded manner.

RESULTS—Twenty-six of the anticipated 28 subjects have completed the treatment and the follow-up phases. Two patients are presently in the follow-up phase. The treatment and control groups had similar baseline Fugl-Meyer scores (11.1 vs. 8.3; p=0.45). The Fugl-Meyer gain scores at post-treatment were significantly higher for the treatment than for the control group (13.1 vs. 6.5; p=0.05). At 1 and 3 mo follow-up, the Fugl-Meyer gain scores remained higher for the treatment group (1 mo follow-up: 17.9 vs. 9.7; p=0.06; 3 mo follow-up: 22.1 vs 11.6; p=0.08).

IMPLICATIONS—Data suggest that active repetitive movements induced by neuromuscular stimulation enhance the motor recovery of acute stroke survivors.

[86] STIMULATOR FOR TREATING POST-STROKE SHOULDER SUBLUXATION

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PURPOSE—Develop a miniature, programmable, multichannel percutaneous stimulator and assess the feasibility of using the device to treat post-stroke shoulder subluxation.

METHODOLOGY—The stimulator circuitry was designed around a low-power, high-performance microcontroller. The electrically programmable and electrically erasable read-only memories inside the microcontroller hold the general operational instructions and the patient-specific protocols, with the latter being changeable by physicians or patients. The current driver, along with the amplitude controller, converts the digital commands from the microcontroller to the analog charge-balanced, current-regulated biphasic stimuli. All of the stimulus outputs are coupled to the electrodes through isolation capacitors to ensure charge balance, and prevent damaging direct current from flowing through the electrode and tissue. Two-high efficiency DC/DC converters are used to generate the 3.3-V operation voltage for the microcontroller and the 33-V compliance voltage for driving up to 20-mA current through the electrode-tissue system. The electronic circuitry of the stimulator was assembled using high-density, surface-mount technology to reduce the size of the device. Implant-grade tantalum capacitors were used for output isolation to ensure safety. The circuit board was packaged in a plastic enclosure originally designed for a pager. Three push buttons are provided for user control and stimulation programming. A liquid crystal display panel shows operation modes, stimulation parameters, and battery status.

RESULTS—Ten stimulators were assembled and bench tested. The characteristics of the output pulses were verified against the design specifications. A typical stimulation waveform of 12 mA, 250 μsec, with a frequency of 12 Hz was recorded by a digital oscilloscope. The programmability of the stimulation parameters was also tested. The stimulator was field tested among acute and chronic stroke survivors with painful shoulder subluxation. The stimulator provided excellent acute reduction of the shoulder subluxation with minimal to no discomfort. Due to its small size and low weight, subjects were able to receive the stimulation during ambulation. Field testing in a limited number of subjects indicates maintenance of shoulder reduction and decrease in pain after 6 hrs of stimulation per day for 6 wks.

IMPLICATIONS—Preliminary results suggest that neuromuscular stimulation via a miniature percutaneous stimulator is well tolerated by stroke survivors and is effective in treating post-stroke shoulder subluxation.

[87] MULTICHANNEL IMPLANTABLE SYSTEM FOR NEURAL CONTROL

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PURPOSE—The aim of this project is to implement and evaluate an advanced neuroprosthetic system for restoration of hand-arm function in subjects who have sustained cervical level spinal cord injury (SCI). The neuroprosthesis will provide the person with C5 tetraplegia with control of grasp and release and elbow extension by electrical stimulation of the paralyzed muscles. These functions will enable the user to regain the versatile manipulative functions which will increase his or her ability to perform activities of daily living (ADL) independently.

METHODOLOGY—The neuroprosthesis consists of a 16-channel implanted stimulator-telemeter, an implanted joint angle sensor (IJAT), and two channels of myoelectric signal acquisition. The power and signal processing is provided by an external control unit through a bi-directional radiofrequency link. Since the only externally worn component is the RF transmitting coil, the issues of sensor mounting and maintenance of cabling are greatly reduced from other neuroprosthetic systems.

The implanted system will be implemented in C5 level SCI to provide grasp/release and reaching functions. Epimysial or intramuscular electrodes will be placed on the muscles of the thumb and fingers, including the finger intrinsic muscles, to provide palmar and lateral grasp patterns. Stimulation of the wrist extensors will be used to provide wrist stabilization or to augment weak voluntary wrist extension. Stimulation of the pronator quadratus and triceps muscles will be used to provide forearm pronation and elbow extension, respectively.

The user will control the neuroprosthesis through generation of voluntary movements or muscle contraction. The control scheme will be customized to maximize use of the individual's available function. The IJAT can be placed in the shoulder or wrist and serve as a proportional control of grasp. The myoelectric signal can be used to provide logic commands, or processed to provide proportional control.

Outcome evaluations will measure the function of the neuroprosthesis components and the performance of users in grasp-release tests and ADL. These tests will allow statistical comparisons of the user's abilities before surgery with those achieved after surgery, both with the neuroprosthesis turned on and turned off. The results of this project will demonstrate the feasibility of a totally implanted neuroprosthesis and the significant improvements in hand function achieved through its use.

FUTURE PLANS —This project will result in completed development of all components of the neuroprosthetic system, the evaluation of the system in bench and *in vivo* testing, and the evaluation of its efficacy in one individual. The telemetry system and the implanted joint angle transducer have completed development. Prototype myoelectric signal processing circuitry is currently being tested *in vivo*.

The proposed system also has application in the efforts to provide standing and walking in thoracic level SCI, stroke, and head injury. These types of applications have been considered in defining the proposed system, so that it will be versatile across different clinical applications.

[88] MECHANICAL EFFECTS OF MUSCLE TENDON TRANSFER AND FUNCTIONAL NEUROMUSCULAR STIMULATION

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PURPOSE—Tetraplegia due to cervical spinal cord injury (SCI) results in the loss of voluntary control over a number of muscles of the hand and arm, severely limiting the ability to perform many routine activities of daily living and work independently. Tendon transfer surgery can be used to restore voluntary control over some arm and hand functions by detaching a nearby donor muscle (remaining under voluntary control) from its normal connection to the skeleton and reattaching it to the tendon of a paralyzed muscle that normally provides the desired function. The specific objectives of this project are to evaluate the ability of a posterior deltoid-to-triceps tendon transfer surgery to restore voluntary control over elbow extension function in individuals with SCI, to measure and assess the impact of this surgery on the other functions of the limb, to examine adaptation in the neural control of the limb in response to the muscle transfer, and to identify and evaluate changes to the surgical procedures which could improve the ultimate functional outcome.

METHODOLOGY—In one set of experiments, the ability of individuals with SCI and subsequent tendon transfer surgery to produce adequate elbow extension moments is measured. The forearm of the subject is fixed to an experimental device so that the elbow and shoulder rotate in a horizontal plane at the level of the glenohumeral joint. Isometric elbow and shoulder moments generated by the subject can then be measured for different combinations of elbow and shoulder angles using a 6-axis force-moment transducer mounted at the interface between the subject and the fixture. In another set of experiments, subjects are seated with their arm attached to the endpoint of a specially designed robotic manipulator. This manipulator is used to generate constant load forces that the subject must balance in order to maintain a desired hand position and to impose small random force perturbations that allow the estimation of the stiffness properties of the arm. The identified stiffness properties are directly related to the postural stability of the arm and can also be used to localize deficits which limit performance.

PROGRESS—We have actively begun experiments to measure the elbow extension strength and its dependence on elbow and shoulder angles in SCI subjects with posterior deltoid-to-triceps transfers. The experimental and analytical methods developed to measure human arm stiffness have been validated using known mechanical systems, and initial stiffness measurements have begun using control subjects.

RESULTS—Elbow extension strength was found to vary widely (from less than 1 Nm to greater than 16 Nm) across subjects, and to depend on the level of SCI. Elbow extension moment was also often found to be highly dependent on both elbow and shoulder angles, in a manner consistent with the length-tension properties of the posterior deltoid muscle. Unfortunately, paralysis and weakness in other shoulder muscles in these subjects force them to adopt arm positions for which the transferred posterior deltoid is shortened and therefore at a mechanical disadvantage. We have also validated the experimental and analytical methods used to estimate endpoint arm stiffness. We have successfully identified a number of known mechanical systems, and preliminary results from controls indicate that the stiffness properties of the elbow-shoulder system operating in a horizontal plane are well characterized by a two-input, two-output linear system. Arm stiffness parameters vary with the size and direction of the load that must be balanced by the subject.

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C. Lower Limb Applications

[89] FUNCTIONAL ELECTRICAL STIMULATION OF SPINAL CORD INJURED PATIENTS: EFFECTS ON MUSCLE BLOOD FLOW AND METABOLISM

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PURPOSE—The purpose of this project is to study the effects of functional electrical stimulation-induced lower extremity cycling (FESILEC) on persons with complete, spastic spinal cord injury (SCI) and determine the therapeutic benefits of this form of rehabilitation.

METHODOLOGY—Subjects participated in a 24- to 48-session training protocol on a computerized REGYS ergometer, powered by lower extremity muscles and activated by cutaneous electrodes. Muscle blood flow (MBF) was studied with $H_2{}^{15}0$ PET, muscle metabolic response with ^{31}P magnetic resonance spectroscopy (MRS), muscle fiber type with histo- and biochemistries of biopsies, and muscle mass with CT and MRI scans.

PROGRESS—In our studies on $H_2{}^{15}0$ PET MBF, a new methodology for the quantitative measurement of MBF, has been developed by using the time-activity curve of the PET image of the superficial femoral artery as the input function in the autoradiographic equation. New SCI and control subjects have been recruited to compare their MBF responses to unloaded and loaded (30 percent of maximum) FESILEC and voluntary exercise respectively. SCI subjects are being studied before and after FESILEC training to test for possible training effects on the MBF response.

The muscle mass of 14 SCI subjects was studied with serial CT and MRI scans of the lower limbs and followed up for periods ranging from 100 to 541 days while on a regular regime of FESILEC. Results showed highly significant increases in cross sectional areas of the following muscles in transverse CT scans measured at the first follow-up period. The percent increase over baseline (before FESILEC started) and statistical significance are indicated in parenthesis: rectus femoris (31 percent, $p=0.000024$), sartorius (22 percent, $p=0.021$), adductor magnus-hamstrings (26 percent, $p=0.00018$), vastus lateralis (39 percent, $p=0.0019$), vastus medialis-intermedius (31 percent, $p=0.006$). Cross sectional area of adductor longus and gracilis muscles did not change. Later follow-up periods showed a stable cross sectional area in the involved muscles. In conclusion, muscles that were directly stimulated achieved a significant increase in mass.

Four SCI subjects and three controls have been recruited for the MRS and muscle biopsy study. To date, evaluation of the muscle metabolic response to one-legged exercise using ^{31}P MRS before and after FESILEC training has been completed in two subjects, with a third subject in the middle of the training protocol. For the same supine exercise at MID, PCr fell 10 percent less and Pi rose 23 percent less, compared to BL. Pi/PCr was 27 percent lower (0.67 MID vs. 0.92 BL), and end-exercise pH was much less reduced (6.71 MID vs. 6.29 BL).

Less voltage was required to elicit contractions at MID compared to BL. Similar results to those at MID were observed at POST. The attenuated changes in PCr, Pi and pH, and reduction in stimulation voltage for the same work rate following FESILEC training suggest that training adaptations did occur in the contracting muscles in those patients tested to date.

Muscle biopsy was taken from the vastus lateralis muscle at the PRE and POST time points. Tissue samples were separated into two portions. One was immediately frozen for subsequent analysis of citrate synthase, a marker of tissue oxidative capacity, while the second was prepared for staining to determine muscle fiber types I, IIa and IIb by myosin ATPase activity at different pH. Results at PRE revealed almost complete absence of type I fibers (<5 percent), compared to control population (average about 40–50 percent). FESILEC training did not alter fiber type composition in the exercised muscles (type I fibers still <5 percent of total). Determination of citrate synthase activity will be performed in the future as a batch when more samples are available.

FUTURE PLANS—We plan to complete work in the areas of muscle blood flow, ^{31}P MRS, and muscle histo- and bio-chemistries.

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[90] FES-AIDED PARAPLEGIC GAIT USING A CONTROLLABLE FRICTION BRAKE

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PURPOSE—Restoration of gait to persons with paraplegia using functional electrical stimulation (FES) is a challenging problem. One difficulty is controlling the FES system for stability and smooth gait. It is possible to improve walking function using surface stimulation by adding a mechanical orthosis in combination with the FES. Based on preliminary work of our group, we have developed such a hybrid system for functional FES-aided gait. The orthosis contains controllable friction brakes at the joints, the purpose of which is to shift the burden of controlling the gait trajectory from control of the stimulated muscles to control of the brake, a well-behaved mechanical element. To evaluate brake designs and performance, we are testing and comparing the ability of persons with paraplegia to achieve FES-aided gait both with and without the orthosis. The assessment includes kinematic, dynamic, and metabolic variables.

PROGRESS—We have designed and constructed a wearable orthosis that can apply controlled braking loads to the knee and hips. The orthosis structure is fabricated from machined aluminum and chromoly tubing. Braking loads are applied by magnetic particle brakes coupled to the joints through an Evoloid gear transmission. Joint position and torque are measured by sensors. The entire system is controlled by a PC connected to the brace by a long umbilical cable.

The orthosis has been tested on two subjects with paraplegia (one extensively) at the West Roxbury VA Medical Center, and on three at the Minneapolis VA Medical Center. Quantitative results from the first subject demonstrated gait for longer distances, reduced heart rate, and improved joint trajectory control when compared to FES gait without the brace. The other subjects demonstrated some, but not remarkable, improvements when using the brace.

FUTURE PLANS—We are continuing to test the system on additional SCI subjects, building a second-generation orthosis that uses more energy efficient brakes and incorporates small DC motors at the hips to aid in hip flexion, and developing a product design process for producing commercial versions of the brace. Investigative trials will take place at the VA Medical Center in Minneapolis, MN.

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[91] OUT-OF-LABORATORY, FEEDBACK-CONTROLLED FNS FOR LOCOMOTION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B683-2RA)*

PURPOSE—The purpose of this research is to develop and evaluate improved methods of functional neuromuscular stimulation (FNS) for locomotion in complete paraplegic subjects. The goal of this improvement is to make possible the use of FNS systems outside of the laboratory by compensating automatically for perturbations such as changing surfaces, disturbances, and internal changes such as muscle fatigue.

METHODOLOGY—Improvements to the current FNS locomotion system take the form of a feedback control system. Sensors worn by the subject provide signals from which decisions concerning stimulation patterns can be made by a control system consisting of three primary components: the *gait event detection module* processes the sensor signals through a fuzzy logic rulebase, to determine the phase of gait while the patient is walking; *the gait evaluation module* uses this information and the sensor information to determine if an anomaly has occurred during walking which requires a change to the stimulation being sent to the patient's muscles; and the *pattern adjuster module* then generates the adjustment in the stimulation pattern.

PROGRESS—Recent work has resulted in the development and testing of real-time gait event detection software. Performance is improved using a hierarchical approach. Gait event detection rules that have been learned from prior experimental trials (using fuzzy system identification) provide an initial estimate of phases of gait from sensor data. These estimates are then interpreted by supervisory rules, resulting in detection of gait events (such as heel strike and toe off).

Hardware and software for a microprocessor-based stimulation parameter controller have been developed. This unit is based upon a Pentium PC which acquires and processes up to 64 channels of analog signals. It communicates with the existing portable microprocessor-controlled 48-channel external stimulator using a high-speed digital interface.

FUTURE PLANS—This technology is being adapted for simultaneous use (in a paraplegic user) with two 8-channel implanted stimulators.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[92] RESTORATION OF GAIT IN ACUTE STROKE PATIENTS USING FNS

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PURPOSE—Stroke is the leading cause of disability among adults in the United States, and conventional rehabilitation post stroke is inadequate to restore safe, independent gait for many persons. The purpose of this project is to determine the efficacy of Functional Neuromuscular Stimulation (FNS) with implanted (IM) electrodes in improving lower limb motor recovery and gait pattern of persons who have had acute stroke.

We are testing the efficacy of the FNS-IM system in stroke by making comparisons of treatment outcome for three different interventions: conventional therapy; conventional therapy + surface FNS; conventional therapy + FNS using IM electrodes. Additionally, we are comparing FNS-gait with voluntary gait at the close of the treatment protocols.

METHODOLOGY—Thirty subjects in each of the three treatment groups are being treated for 6 mo; treatment begins at least 2 wks post stroke and when the individual is medically stable. FNS exercise and FNS gait training protocols are used.

Outcome measures are classified into three levels of physical function of increasing difficulty. The first level is voluntary movement at a single joint with the body in a static position. The second level is voluntary motor control during walking. The third level is functional capability at home and work. Data are collected every 6 wks during the 6 mo of treatment. Carry-over effects are monitored at two additional data collection sessions at 1 mo and 1 yr following the end of the treatment period.

IMPLICATIONS—Results of this study have the potential to provide the following clinically applicable information:

1. A definitive answer regarding a three-way comparison of efficacy of sophisticated FNS technology: multichannel FNS-IM system versus multichannel surface FNS system versus conventional therapy alone.
2. Quantification of the comparative long-term benefits of each of the three interventions and preliminary predictive criteria regarding suitability of persons with acute stroke for the implanted FNS orthotic system.
3. Quantification of results of FNS exercise and gait training protocols for the acute stroke population.
4. Delineation of the FNS hardware and software specifications required for an FNS treatment system suitably reliable and simple for deployment to multiple regular clinical institutions.

[93] FES MOBILITY IN PARAPLEGIA: RF-CONTROLLED IMPLANTED SYSTEM

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PURPOSE—The overall goal of this project is to enhance the personal mobility of individuals with complete thoracic level spinal cord injuries (SCI) with functional electrical stimulation (FES). An implantable system is being developed to provide individuals with T4-T10 paraplegia with the ability to perform stable standing, walking for short distances, and household mobility maneuvers with a minimum of bracing and personal assistance. The purpose is to establish the clinical and technical components required to introduce implantable FES systems safely and effectively into the home and community environments in larger scale clinical trials.

METHODOLOGY—The walking mobility system consists of two CWRU/VA 8-channel implanted receiver/stimulators (IRS-8) for a total of 16 stimulus channels. Stimulation is delivered via 14 epimysial electrodes deployed bilaterally into the knee and hip extensors (quadriceps, gluteus maximus, semimembranosus, posterior adductor), hip flexors (sartorius, tensor fasciae latae), and ankle dorsiflexors (tibialis anterior). Additionally, two intramuscular electrodes are surgically implanted near the L1/L2 spinal roots to activate the erector spinae and iliopsoas muscles simultaneously. The system is installed in two surgical procedures. Each 8-channel subsystem is isolated from the other to minimize the risk of infection and mechanical damage, as well as to simplify service.

Following a period of immobilization and inactivity after surgery, reconditioning exercise is prescribed to re-establish strength and endurance. This is followed by a rehabilitation phase consisting of tilt-table standing, progressing to standing and stepping in parallel bars or rolling walker. Finally, participants are qualified to use the dual-implant system at home and in the community.

A new wearable external control unit (ECU) generates power and command signals to coordinate the actions of both stimulators via two transmitting coils taped to the skin surface over the implants. The ECU is rechargeable, ergonomic, and serially programmable from a laptop personal computer.

Three individuals with motor complete thoracic paraplegia will be recruited to participate in this study. Screening and evaluation techniques will be formalized and standardized in anticipation of future multicenter trials.

PRELIMINARY RESULTS—This system has been successfully implanted in the first volunteer who sustained a motor-complete SCI at the level of T10 approximately 5 yrs prior to surgery. In November 1996 the eight posterior electrodes were installed and leads routed to the abdominal area where they were capped to prevent tissue ingrowth; 2 wks later, the anterior muscles were implanted and all electrodes connected to the IRS-8 devices. Following a period of inactivity, the subject progressed from exercise to standing and stepping with the system. Electrode thresholds stabilized and stimulated contractions are sufficiently strong for functional activities. The subject is currently using the system at home to exercise, stand, and walk.

FUTURE PLANS—Results from the first application of the system are encouraging. Although the responses to several electrodes can be improved by refining the surgical technique, the system is operational and adequate for unassisted standing and stepping. A revision is planned to reposition several electrodes to further improve system performance. Changes to the implementation protocol are under consideration to permit a staged approach to system installation. Future recipients will likely receive an 8-channel standing system for extended home use, followed by the introduction of the second implant and instrumentation of the remaining muscles required for walking. Recruiting for additional subjects is ongoing and efforts to solicit clinical partners within the VA system interested in collaborating in a larger scale study will continue.

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[94] DEVELOPMENT OF A CLOSED LOOP FES SYSTEM AND APPLICATION TO STANDING UP MOVEMENT FOR PERSONS WITH PARAPLEGIA

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PURPOSE—The purpose of this study is to develop and apply a closed-loop control system for functional electrical stimulation (FES), in order to train persons with paraplegia to stand up by means of muscle stimulation and a dedicated mechanical device for partial weight relief.

METHODOLOGY—The system is based on a PC, a programmable 8-channel stimulator, a software controller and electrogoniometers. A PID software regulator has been experimentally realized and used to control the stimulator. The controlled variables are the knee angles of both legs (measured by means of flexible electrogoniometers), interfaced by a dedicated board with the PC. The actual angles are compared with the desired ones in real time, and on the basis of their difference, the PID controller modulates the width of stimulation pulses produced by the stimulator. Surface electrodes are used to induce artificial contraction of the quadriceps muscles of both legs in order to extend the knees and thereby obtain a standing-up movement. A mechanical device for weight relief, consisting of a see-saw system, has been developed and equipped with a counterweight that is decreased during the training progress of the subject. Two working configurations have been considered: tracking of a prefixed knee angle trajectory and master-slave configuration, in which the tracked angle is caught in real time by an electrogoniometer from another joint (or even from the physioterapist).

PROGRESS—Applications of this technique to the training of persons with paraplegia in FES-induced standing-up movements has been considered. The idea is to treat those selected for FES walking application before the beginning of the specific training program in walking, in order to produce an increase in muscle strength and fatigue resistance and, at the same time, to obtain a recovery of standing posture, with positive effects on the musculo-skeletal, cardiorespiratory, and vestibular systems. Advantages of this system are its intrinsic safety characteristics and the possibility of modulating the load on stimulated muscles by modifying the counter weight of the see-saw system.

Specific attention in reference trajectory has been posed. A biomechanical model of the entire system (subject and see-saw device) has been developed and used to obtain the optimal knee trajectory during sit-to-stand movement from the point of view of knee joint torque minimization. The repetition of standing-up and sitting-down movements is considered with permanence period in sitting and standing posture. Once the training proceeds, the total duration of exercise cycles is increased and the counter weight is decreased, following subject-specific improvements.

PRELIMINARY RESULTS—Up to now, one subject with a complete traumatic spinal cord lesion at T5-T6 level has been included in this project. After 2 mo of 1 hr daily training sessions, 4 times weekly, he increased his thigh diameter about 15 percent and is able to stand up and sit down 7 times with a weight relief of half of his body weight. Fatigue resistance to muscle stimulation is improved too. The closed-loop controller appears robust to both external and internal disturbances like electrode movements and muscle fatigue, respectively.

FUTURE PLANS—The inclusion of further subjects in the study is foreseen. The use of the system in the master-slave configuration will be investigated too, using elbow angle as reference signal for the knee angle during standing, since in healthy subjects we found a good correlation between knee and elbow angle during this movement.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[95] PARAPLEGIC WALKING MADE PRACTICAL WITH FNS AND ORTHOSES

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PURPOSE—We seek to determine whether the combination of eight channels of implanted functional electrical stimulation (FES) and a functionally activated trunk-hip-knee-ankle-foot orthosis can result in a practical mobility aid for use by the individual with complete paraplegia. Our focus is to provide sufficient control to the existing FES capability to allow meaningful functions, such as crutch walking and stair climbing, and develop a brace system acceptable to the person and to society, from the aspects of function, reliability, safety, ease of use, appearance, and cost.

METHODOLOGY—We shall fit multiple subjects with the combination of an 8-channel radio frequency (RF) controlled and powered implantable stimulator, or a percutaneous FES system, with a prototype low weight, functional orthosis having active, computer-controlled joint locks. A hybrid orthosis will result from combining this technology with expertise in electromechanical brace design from CWRU, Henry Ford Hospital of Detroit, and New York University (NYU). The physical therapist will utilize accepted and modified outcome assessment and energy consumption measures to determine the user's ability to function in the household or the community at large.

PROGRESS—We have developed the surgical techniques for implantation of an 8-channel RF-powered-and-controlled FES and implemented them in three subjects participating in related projects. The first implantation of the RF stimulator/receiver in a subject participating in the hybrid FES program is scheduled for Fall 1997. After a thorough review of the state of the art in orthotic systems, a design team has constructed a platform orthosis.

RESULTS—Six subjects with paraplegia, injury levels T-1–T-11, have participated in a study to evaluate the functional capabilities of a computer-controlled hybrid orthotic system. The subjects have learned to use the custom-built reciprocal gait orthosis without stimulation and with electrical stimulation activating between 4 and 16 muscles. Outcomes were scored with standard physical therapy measures, including the Tinetti test, a timed get up and go, Borg energy exertion, and the functional index measure. Subjects have successfully accomplished sit to stand, stand to sit, and walking maneuvers measured for time, speed, distance, and metabolic output. FIM scores indicated that system users would become slightly more independent in mobility categories. Perceived exertion as a measure with the Borg scale indicated that use of the bracing system with FES was easier than without stimulation. Subjects were able to exhibit distance walking that would allow limited but useful ranges of 500 m at average speeds of 0.2–0.3 m/s. Walking speeds for 30- and 50-m distances reached 4 to 4.5 m/s. Metabolic output measured in the light work region of 7 METs. Additionally, walking distance with stimulation were two times or greater than those of nonstimulated reciprocal gait.

IMPLICATIONS—A less constrained brace, combined with an implantable FES system, will, as indicated by these results, allow a completely paralyzed user to attain a limited level of community ambulation.

[96] UNASSISTED STANDING BY FUNCTIONAL ELECTRICAL STIMULATION

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Sponsor: *Neural Prosthesis Program, National Institute of Neurological Disorders and Stroke, National Institutes of Health*

PURPOSE—The long-term goal of this project is to develop methods to provide brace-free, energy efficient standing for persons with complete thoracic level spinal cord injuries (SCI) via functional neuromuscular stimulation (FNS). The objectives are to define the fundamental requirements, develop the control strategies, and understand the factors limiting the performance of systems designed to automatically resist reasonable disturbances to balance and free the upper extremities for manipulating objects in the environment while standing. These objectives are being addressed through anatomical modeling, dynamic modeling, and controller development, simulation, and optimization, and experimental demonstration of new control structures. This work is conducted in partnership with collaborators at Northwestern University and the University of Kentucky.

METHODOLOGY—A biomechanical model of the lower extremities and torso that accurately reflects the actions of FNS on paralyzed muscle and incorporates the behavior of non-ideal and commercially available body-mounted sensors is being developed. The model will be employed to construct dynamic simulations and perform optimization procedures to investigate the theoretical behavior of various FNS control systems for providing automatic postural adjustments. Predictions from the simulations will drive the implementation and experimental demonstration of the postural control systems in human volunteers. Results of human trials will be used to refine the model or reformulate the control simulations.

The methods for automatic control of posture are based on the assumption that no single control strategy will be sufficient to achieve the requisite standing performance. The inherent passive stiffness of the joints and the responsiveness provided by the active stiffness resulting from low-levels of continuous co-activation of agonist-antagonist muscle groups will be used to help insure stability. A variety of controllers that modulate stimulation in response to, or in preparation for, a change in postural load will be simulated, implemented, and tested with the aim of integrating the best elements of each into a coordinated artificial postural control system.

Both fixed-parameter, and sensor-based control strategies will be investigated. Fixed-parameter controllers will include systems that slowly vary the position of the center of mass over the base of support, or that allow the user to select a posture and define the stiffness in a preferred direction in advance of a disturbance or voluntary movement of the upper extremity. Sensor-driven systems will include joint angle and acceleration-based controllers to mimic proprioception and vestibular-like responses.

PROGRESS—A biomechanical model of the spine and trunk is under construction and will be integrated with the existing computer representation of the lower extremity musculo-skeletal system. Anatomical specimens from the erector spinae, quadratus lumborum, and rectus abdominis have been collected and muscle architecture is being parameterized for inclusion in the model. Methods to compute system dynamics from records of muscle activation patterns have been established, and initial simulations of simple control systems are being completed. Methods to calculate disturbances to posture from volitional arm movements have also been established and will be used to simulate real-world perturbations at the shoulder. Algorithms to compensate automatically for changes in muscle recruitment properties have been developed and tested in simulation.

FUTURE PLANS—Anatomical modeling and simulation will continue. Immediate plans include experimental determination of joint stiffness and other model parameters in individuals with spinal cord injuries. Optimization procedures and sensitivity analyses are being conducted with the existing biomechanical model. Baseline performance of simple open loop systems for standing will also be determined and used for comparison with the advanced control systems under development.

[97] IMPLANTABLE FNS SYSTEMS FOR STANDING TRANSFERS

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PURPOSE—This project is designed to provide standing and transfer function to individuals with low-cervical or high-thoracic spinal cord injury (SCI) via an implanted functional neuromuscular stimulation (FNS) system. Injuries at these levels compromise mobility, increase dependence on families, caregivers, or assistants, and compound the risk of medical complications secondary to paralysis. Conventional transfers are problematic for individuals with elderly spouses or caregivers who lack the strength to assist with the lifting phases of the maneuvers. The long-term objective of this project is to introduce into clinical practice a neuroprosthesis that will allow individuals with SCI to stand and transfer with minimal assistance, thereby increasing independence, personal mobility, and overall health and well-being.

METHODOLOGY—A surgically implanted FNS system for standing and transfers is being implemented in five volunteers with SCI between the levels of C6 and T4. The system consists of epimysial and surgically implanted intramuscular electrodes, and the CWRU/VA 8-channel implantable receiver/stimulator (IRS-8). A wearable external control unit (ECU) provides power and command signals to the implant.

After a period of preparatory exercise with surface stimulation, the IRS-8 is installed in a single surgical procedure. Epimysial electrodes are implanted bilaterally into the quadriceps (vastus lateralis/intermedius), gluteus maximus, and semimembranosus or posterior portion of the adductor magnus. Intramuscular electrodes are inserted at the level of the L1/L2 spinal roots to activate the erector spinae. Electrode leads are routed to sites on the abdomen and connected to the IRS-8, which is sutured to the abdominal fascia. After 2 wks of immobilization and bedrest, subjects are released to home for an additional period of restricted activity before reconditioning exercise is initiated 6 wks postimplant.

Outpatient rehabilitation consists of progressive resistance and closed-chain exercise followed by standing, balance, and transfer training using the implanted neuroprosthesis. Functional outcomes are assessed with customized ratings of system usability, and measures of effort and assistance required to complete maneuvers with and without FNS. Long-term follow-up of system use and performance in the home and community environments continues for a full year after demonstrating safety and proficiency with the system.

PRELIMINARY RESULTS—Quantitative anatomical dissections on seven fresh frozen cadaver specimens resulted in standardized and repeatable approaches to the key muscles of interest. These surgical techniques were verified through intra-operative tests performed during regularly scheduled clinical procedures. This effort culminated in the successful implantation of the standing/transfer neuroprosthesis in the first study volunteer July 1997.

The first implant recipient is a 37-year-old male with complete motor paraplegia resulting from a T4 SCI sustained in an industrial accident 4 yrs prior to implantation. All incisions from the implant procedure healed without incident, and the implanted components are intact and operational. The electrodes exhibit stable thresholds and produce contractions of sufficient strength for functional activities. The subject is currently in the exercise and rehabilitation phases of the protocol, and standing, balance, and transfer training are scheduled to begin fall 1997.

FUTURE PLANS—The exercise, rehabilitation, and training phases for the first subject will be followed by home visits to facilitate the system's incorporation into his daily routine. New evaluation and assessment scales currently under development will be applied and refined at that time. Recruiting for additional implant recipients will continue until a total of five local subjects are enrolled and implanted in the next 2 yrs. Immediate plans also include the field testing and production of new external electronic components.

RECENT PUBLICATIONS FROM THIS RESEARCH

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A reusable, self-adhesive electrode for intraoperative muscle stimulation in the lower extremity. Moss JD, Bhadra N, Triolo RJ. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press, 1997. p. 535–7.

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Using selective electrical stimulation of the quadriceps to improve standing in paraplegia. Uhlir J, Triolo RJ. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press, 1997. p. 313–5.

Implanted FNS systems for assisted standing and transfers for individuals with cervical spinal cord injuries: clinical case reports. Triolo RJ, Bieri C, Uhlir J, Kobetic R, Scheiner A, Marsolais EB. Arch Phys Med Rehabil 1996;77(11):1119–28.

[98] MUSCLE COACTIVATION IN TRANSCUTANEOUS FES

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Sponsor: *The Segal Foundation, Israel*

PURPOSE—We seek to determine whether the coactivation response to transcutaneous stimulation of the quadriceps significantly affects the knee torque.

METHODOLOGY—A dynamic model of the paralyzed thigh is being developed for the case where the hamstrings muscles are indirectly activated as a result of supramaximal transcutaneous stimulation of the quadriceps. Simultaneously to torque, the EMG of the above-mentioned muscles are measured and serve to evaluate the neural excitation of each muscle. An iterative optimization procedure is developed to determine the force distribution between the quadriceps and hamstrings muscles. Specifically, the hamstrings recruitment level and the muscle force history of both muscles are determined.

The experiments include 3 min supramaximal sustained transcutaneous FES of the quadriceps muscle of the right thigh. The measurements include knee joint torque and EMG of the quadriceps and hamstrings. The

M-wave peak-to-peak amplitudes from both quadriceps and hamstrings are curve-fitted, using a tri-exponential analytical function. Neural excitation is defined for each muscle as the ratio between the temporal peak-to-peak amplitude and the maximum peak-to-peak amplitude. The force histories (initial iteration based on previously measured fatigue profiles) of the above-mentioned muscles and the recruitment level of the hamstrings are estimated by using an iterative procedure. This procedure is aimed at minimizing the error between the measured and the estimated knee torques. The muscle specific tensions are assessed for two different solution cases: 1) equal values in both the quadriceps and hamstrings; and 2) higher values in the trained quadriceps compared to that of the untrained hamstrings.

RESULTS—The estimated recruitment level of the hamstrings is found to be 18 percent. The average values (n=5) of the recruitment levels are 12 percent (SD=6) for solution case 1, and 20 percent (SD=5) for solution case 2. The predicted maximal forces in the quadriceps (n=5) are 16 to 32-fold higher than in the hamstrings for solution case 2. For solution case 1 the ratios were 12 to 32-fold higher.

The results obtained for either of the combinations of specific tensions demonstrated that the estimated torque about the knee is dominated by the quadriceps torque. It is therefore concluded that a paralyzed thigh is not affected by the coactivation response to transcutaneous stimulation of the quadriceps.

FUTURE PLANS—A developed model of force recruitment based on the distribution of the electric field in a layered medium will be used for comparison with the above-mentioned results.

V. Geriatrics

[99] RELIABILITY AND VALIDITY OF ACCELEROMETRIC GAIT AND BALANCE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E601-3RA)*

PURPOSE—The sense of balance declines with age due to combined vestibular, proprioceptive, and visual losses, resulting in impaired mobility and increased risk of injurious falls. A wearable accelerometric instrument has been developed to record movements outside the laboratory, identify motion patterns that accompany loss of balance before a fall occurs, warn the individual of pre-fall behavior, and if necessary, signal that the wearer has fallen. Accelerometry is clinically useful as a diagnostic tool to quantify hitherto qualitative measures of balance, as a biofeedback device during therapy and as a fall-prevention aid and balance orthosis for fall-prone elderly individuals.

Researchers, clinicians, and potential industrial partners familiar with accelerometry have noted the need for rigorously testing the reliability and validity of this device before it can become a routine clinical tool. In this phase of the project, we will establish statistical reliability and validity by comparison of accelerometry with conventional laboratory gait and balance measures (force platform, goniometry, and video imaging) using subjects having well-defined gender, age, and mobility status.

METHODOLOGY—The accelerometric motion detection system consists of two small 3-axis sensors attached to both corners of eyeglass frames to measure head motion, and two sensors above each hip on a belt at the waist, along with a self-contained data acquisition package. An infrared remote control is used to command the wearable unit, so the wearer is unencumbered by cables. In a typical test, subjects perform tasks derived from qualitative balance assessment protocols, including: stand eyes open, then closed; ascend stairs, turn, then descend; rise from and sit in chair; normal walk 10 m; tandem (toe-to-heel) walk 3 m; walk over obstacles 1 m apart.

Among the factors that affect consistent interpretation of accelerometric data are: 1) mechanical and electronic stability, 2) installation and calibration (inter-rater reliability), 3) test-retest reliability, 4) accuracy vs. accepted techniques (concurrent validity), and 5) presentation of results derived from accelerometric data in a form comparable to currently accepted measures. We will enroll and test on at least three occasions 240 control subjects who are either fit or deconditioned. Subjects will be grouped by gender and age decade (60s, 70s, 80s); all will have stable mobility status. Overall differences between initial and retest values and differences between accelerometric and conventional measures will be compared using appropriate statistics.

PROGRESS—Work has continued on a second-generation device that incorporates pulse-output acceleration sensors, two semi-custom digital signal processing chips, and PCMCIA memory cards. Data from subject populations comprising stroke, Parkinson's disease, and hip arthroplasty patients, as well as controls induced to stumble in the laboratory, are being analyzed. An instructional videotape has been produced for self-teaching of nonlocal users of the system. Local collaborators have used the method in a study of therapeutic interventions in fall-prone elderly subjects, and nonlocal researchers have studied fatigue in walking by the elderly and standing balance in a variety of subjects. Collaborations have been established to develop special-purpose devices for identifying and preventing lateral falls likely to result in hip fracture and for combined head- and eye-tracking for vestibular research.

FUTURE PLANS—In addition to its use as a diagnostic and therapeutic tool for balance-impaired elderly individuals, real-time accelerometric pattern analysis and feedback can be applied to prevention of reinjury following occupational rehabilitation, and to athletic training.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Accelerometric motion analysis of balance-impaired elderly subjects. Troy BS, Sabelman Eric E, Kenney DE, Dunn-Gabrielli S.Proceedings of the 19th Annual RESNA Conference; 1996 Jun 7-12; Salt Lake City, UT, 1996. Washington, DC: RESNA Press; 1996.

Upper body motion analysis for amelioration of falls in the elderly. Sabelman EE, Jaffe DL. Workshop on Wearable Computers; 1996 Aug 19-21, Seattle, WA.

[100] PERFORMANCE-BASED PREVENTION/REHABILITATION OF FALLS IN ELDERLY VETERANS

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No report was received for this issue.

[101] AGE-RELATED CHANGES IN THE TRICEPS SURAE STRETCH REFLEX AND POSTURAL CONTROL

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PURPOSE—Hip fractures resulting from fall events in older veterans result in high costs for medical and surgical care, as well as in comprised quality of life. One method to enhance awareness of the location of the center of pressure and fostering controlled excursion through the weight-bearing surface is by providing pressure feedback as a vehicle to constrain or enhance vertical loading or body sway. These last sets of experiments were undertaken to determine whether feedback about vertical loading forces during dynamic angular perturbations among older individuals, both without past incidents of falls and among fallers, led to more substantial abilities to increase vertical loading compared to age-matched controls. Demonstration of increased loading might serve as a basis to facilitate stepping strategies among older people.

METHODOLOGY—All data were gathered using the NeuroCom Equitest device, from which absolute voltage values from force transducers positioned in the corners of a moveable platform were gathered and converted to forces. Each of 12 sessions consisted of 30 angular (66°/sec, 8° arc) toes-up perturbations, with each perturbation presented randomly but requiring subjects to demonstrate less than 1° of sway. After six sessions, subjects were randomly assigned to training or control groups. Training consisted of feedback displayed as a bar graph, the height of which was proportional to the magnitude of sway, starting at a median value of the first 6 sessions. Among nonfallers mean age was 72 for trainers and 73 for controls (total N=11), while among fallers, the mean ages for trainers and controls were 73.8 and 72, respectively. Loading responses were analyzed in 75 msec time bins, designated T1–3 to represent the time of occurrence of segmental, long latency, and integrative responses.

PROGRESS—Data analyses from nonfallers showed that trainers decreased vertical loading relative to baseline with the largest decline occurring in T3. No correlation was seen between loading values and clinical balance test performance. Thus, despite being trained to increase loading, subjects still seek to constrain their responses. To date, there appear to be no statistically significant differences among the two faller groups.

FUTURE PLANS—A more practical approach to using force feedback would be to train for changes in sway rather than vertical loading, and future efforts will be directed toward exploring this approach. In addition, our Tai Chi work has demonstrated that older people can delay the onset of falls with this intervention. We plan to examine whether Tai Chi forms can be better learned and retained through practice on balance devices from which older subjects can receive intermittent feedback.

[102] EXERCISE PROGRAM DESIGNS FOR OLDER ADULTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E825-3RA)*

PURPOSE—This 2-year study will develop an expert system that creates individualized exercise plans for older adults using factors, or determinants, that affect exercise initiation and adherence. These plans can be used by practitioners at VA hospitals and other health care facilities during regular physical examinations and routine medical visits of older adults to help them initiate and adhere to exercise programs. The expert system will focus on personal, environmental, and activity characteristics that act as incentives and barriers to exercise initiation.

METHODOLOGY—A knowledge base of factors and recommended strategies that affect exercise in older adults will be compiled by extensive literature review and critiqued by local and national professionals with expertise in the fields of medicine, exercise physiology, health promotion, exercise psychology, psychometry, and gerontology. Using case study analyses, these professionals will develop a rule base to define the relationships between the determinants and the recommended strategies. The knowledge base will then be translated into a diagnostic questionnaire and implemented as a computerized expert system to be validated by local and national experts.

Case studies of older adults will be analyzed using the expert system. The analyses will focus on examination of the exercise plans created by the expert system in response to each case study subject's profile on exercise initiation and adherence determinants. A priority ordering will be assigned to the determinants based on their importance in creating recommended strategies.

Discrepancies between recommended strategies in the plan and expert opinion will be cross examined until group consensus is reached concerning the appropriateness of the exercise plan developed for each older adult.

PROGRESS—A Physical Exercise Profile (PEP) questionnaire has been expanded to assess 29 determinants that relate to exercise behavior in older adults. The output of the expert system includes a client's report consisting of a customized exercise prescription, recommended strategies, and an exercise knowledge sheet. Another system output is the practitioner's report consisting of the client's exercise prescription, summary of determinants, and exercise preferences.

FUTURE PLANS—We plan to measure the effectiveness of the exercise expert system on exercise habits by examining exercise patterns of two groups of ambulatory elderly individuals, one group receiving the exercise assessment and counseling protocol (EACP). The key behavioral outcome, adherence to an exercise regimen, will be investigated by self-report data using the EACP and by testing of strength, aerobic, and flexibility measures. The second objective is to measure the impact of the EACP on quality of life, health maintenance, and functional status.

[103] BEHAVIORAL AND FUNCTIONAL PROBLEMS IN DEMENTIA PATIENTS WITH SENSORY LOSS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E2044-2RA)*

PURPOSE—This 2-year study will describe the functional and behavioral problems experienced by demented nursing home residents with sensory impairments, analyzing the relationships among cognition, vision, hearing, functional status, and behavioral disturbance in this population. Interventions with the potential to reduce excess disability in self-care functioning and dementia-related behavioral disturbance will be identified. Long-term study results will be used to focus controlled intervention studies.

METHODOLOGY—The familiarity of nursing home staff with the health status and daily functioning of their residents will be coupled with clinical testing to characterize cognitive and sensory status, along with functional and behavioral problems. Quantitative analyses will isolate the relative contributions of cognitive and sensory status, providing an empirical base for expectations about the magnitude of effect of different interventions and laying the groundwork for controlled intervention studies. Observations of the staff regarding possibly efficacious interventions will be identified through the use of focus group methods and combined with expert opinion based upon the empirical findings of the study to identify promising interventions that deserve further study. The project team has particular interest in environmental interventions that will improve the functioning and well-being of residents with dementia and vision loss, as well as in strategies for staff that will enable them to assist individuals in maximizing the benefit they achieve from existing environmental resources. All subjects will be recruited from the ECRC at the Durham VAMC and the ECRC and geripsychiatric program at the Salisbury VAMC. Geriatric and vision researchers at both sites who also have clinical experience with the study population will collaborate in the study.

PROGRESS—The research staff has been trained in data collection protocols. Interrater reliabilities are being established. Current resident populations are being screened to identify the pool of eligible subjects.

INITIAL RESULTS—No data have been collected at this time.

[104] EVALUATION OF INTERVENTIONS TO PREVENT ELOPEMENT AMONG NURSING HOME PATIENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E759-3RA)*

PURPOSE—This study evaluates electronic wanderer alarm systems and access to secure outdoor space—widely used environmental interventions to control elopement or exiting among dementia patients in long term care settings. Questions examined are: Do less aversive alarm signals (voice message) and access to a secure outdoor space affect the frequency of actual or attempted elopement incidents? Is there a difference in the average time that elapses between an incident and staff response with alarms with conventional and less aversive auditory signals? And do less aversive alarm system signals and access to a secure outdoor space impact resident mood and behavior and staff ratings of job stress?

METHODOLOGY—A single subject, multiple baseline methodology was used to collect baseline data, followed by step-wise implementation of two interventions. During the baseline, a wanderer alarm with conventional signal (loud and aversive) was in operation. One intervention entailed modifying the wanderer alarm system signal to a less aversive sound (i.e., verbal announcement that a fictitious staff has a visitor). The second intervention provided wanderers with access to a secure outdoor space adjacent to the unit. Intervention order was varied across sites. The frequency of actual and attempted elopement incidents as well as staff response times were documented by automated video recording at exits from the unit. Standardized instruments were used to measure other dependent variables. The project is being completed at three sites.

PROGRESS—Data collection has been completed at two sites and is underway at the third site. Data coding, including screening videotapes for observational data, and input has been completed at two sites. Data have been reviewed for accuracy, and preliminary data analysis has been completed for one site.

INITIAL RESULTS—Preliminary data on the frequency of incidents and other subject ratings are reported here for the three subjects at one site. The total number of incidents observed for the subjects ranged widely (N= 37, 329, and 868) over the 8 mo of observation. The frequency of incidents was compiled by weeks and compared across phases for each subject. Comparison was by visual inspection of graphed frequencies and examination of mean frequencies and associated 95 percent confidence intervals (box and whisker plots) for each phase by subject. There was a decline in the absolute number of incidents across phases for all subjects. However, box and whisker plots indicate that there was no meaningful decline in the frequency of incidents between the baseline and the first intervention (access to outdoor space) for any of the subjects. For the two most frequent elopers, there was a decline in frequency of incidents between the baseline and the second intervention (verbal message) and between the first and second interventions. These two subjects' gait, balance, and mobility, as rated by clinical staff, changed little during the observation period, suggesting that the observed declines in incidents are not explained by loss of ambulatory function. Although introduction of the interventions appear to have been related to an overall reduction in the frequency of elopement for these subjects, they do not appear to be related to any substantive changes in other domains of disruptive behavior during the observation period. In conclusion, the replacement of an aversive alarm signal with a verbal message appears to be a promising intervention, at least for some demented wanderers. However, it should be noted that the outdoor space feasible at this site lacked some characteristics that are believed to be important in attracting residents at risk of elopement to the space and away from exits.

[105] QUANTITATIVE POSTUROGRAPHY: AGE-RELATED CHANGES IN POSTURAL STABILITY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E720-3RA)*

PURPOSE—Older adults exhibit problems in posture and balance. These disorders predispose the elderly to falls, which are a common cause of trauma and the largest single cause of accidental deaths among the aged. Despite the severity and frequency of this problem, postural instability in the elderly remains a poorly understood phenomenon. In this study, our objective was to study how the natural aging process affects the neuromuscular mechanisms involved in balance control.

METHODOLOGY—We examined 200 healthy subjects (aged 19–90 years) under quiet-standing conditions. Males and females were included. Each subject's postural stability was evaluated using a force platform to measure the displacements of the center of pressure (COP) under the feet. The COP time series were analyzed as one-dimensional and two-dimensional random walks, according to stabilogram-diffusion analysis. Stabilogram-diffusion analysis leads to the extraction of repeatable COP parameters that can be directly related to the resultant steady-state behavior and functional interaction of the neuromuscular mechanisms underlying the maintenance of upright posture.

PROGRESS/RESULTS—Our findings concerning healthy young subjects (<30 yrs) and healthy elderly subjects (>70 years) were consistent with our earlier studies. In general, we found that the steady-state behavior of the open-loop postural control mechanisms in the elderly is more positively correlated and therefore perhaps more unstable: the output of the overall system has a greater tendency to move or drift away from a relative equilibrium point over the short term. In contrast with this result, we also found that the steady-state behavior of the closed-loop postural control mechanisms in the elderly is more negatively correlated and therefore perhaps more stable: over the long term, there is an increased probability that movements away from a relative equilibrium point will be offset by corrective adjustments back toward the equilibrium position. In addition, we found that the elderly utilize open-loop control schemes for longer time intervals and correspondingly larger COP displacements during periods of undisturbed stance. This finding suggests that in the elderly the threshold at which postural feedback mechanisms are called into play is elevated.

[106] RANDOMIZED CONTROLLED TRIAL OF UPPER-EXTREMITY EXERCISE TRAINING IN PATIENTS WITH COPD

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E2010-RA)*

PURPOSE—Randomized controlled trials have demonstrated that lower-extremity (LE) exercise training leads to improved exercise tolerance and decreased dyspnea in persons with chronic obstructive pulmonary disease

(COPD) and is therefore routinely included in rehabilitation programs. Physiologic data suggest that those with COPD may benefit from the addition of upper-extremity (UE) training because of its effect in strengthening shoulder-girdle musculature that serves as accessory muscles of respiration. These muscles are particularly important in COPD patients, whose diaphragmatic function is impaired by lung hyperinflation. Because of the key role of UE activities in daily life and the important contribution of shoulder-girdle musculature in COPD subjects, we hypothesize that UE training may substantially enhance the quality of life (QOL) and functional status of many individuals with COPD. We further hypothesize that these benefits may be greatest in the elderly, whose initial level of fitness is expected to be lower than that of younger persons. The overall goal of the proposed project is to test these hypotheses by means of a randomized controlled trial.

METHODOLOGY—In this trial, clinically stable COPD patients aged 50–79 years are randomized to an experimental group receiving LE exercise training plus unsupported UE exercise training or to a control group receiving LE exercise training alone. Subjects are recruited from the Boston and Brockton/West Roxbury VAMCs. Each training program consists of three 40-min sessions per week for 8 weeks; it is recommended that subjects continue to exercise upon completion of the 8-wk training session. The primary outcome variables include measures of disease-specific QOL, baseline and exertional dyspnea values, and results of a simulated activities of daily living (ADL) test. Other outcome variables of interest include the 6-min walk distance, determinations of maximal O_2, and anaerobic threshold.

PROGRESS—To date, study activities have focused on screening and enrollment.

PRELIMINARY RESULTS—No preliminary information is available yet.

FUTURE PLANS—Approximately 100 subjects will be randomized in this study during the enrollment period. Outcomes will be assessed at three time points: at entry into the study, immediately after the 8-wk exercise program, and 6 mo after completion of the exercise program.

[107] RISING FROM THE FLOOR IN OLDER ADULTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E2023-RC)*

PURPOSE—Difficulty in rising from the floor after a fall is common in older adults; it is associated with substantial morbidity and tends to be underappreciated. Many are unable to get up after a fall without assistance, even though they have not sustained a major injury. Thus, the inability to get up after a fall is not simply a consequence of a fall-related injury. Despite the high risk of difficulty in getting up, few therapists teach older adults how to do it. The purpose of the present study was to determine the ability of older adults to rise from the floor. A secondary goal was to explore how rise ability might differ according to initial body positions and with or without the use of an assistive device. We hypothesized that with increased age and physical impairment, success in rising would decrease, and in successful rises, the rise speed would decrease. We also hypothesized that starting from a hands and knees position and using a low-lying piece of furniture for support would increase floor rise success and decrease the time of successful rises. These data can serve as the basis for understanding how rising from the floor changes with age and with underlying disease-associated impairments and for developing training methods to improve floor rise ability.

METHODOLOGY—We videotaped young adult controls (YA: 12 male, 12 female, mean age 23), healthy older adults (HO: 12 male, 12 female, mean age 73), and congregate housing older adults (CO: 32 female, 6 male, mean age 80) as they rose from a variety of starting positions on the floor. The HO females (n=12, mean age 75) and a subset of the CO females (n=27, mean age 81) were identified for further analyses. Subjects rose from controlled initial body positions (supine, on side, prone, all fours, and sitting), either with or without the use of furniture support. Outcomes included whether subjects were successful in rising, and if they were, the time taken to rise. Subjects also rated their perceived difficulty of the task as compared to the reference task, rising from a supine position.

RESULTS—Older persons had more difficulty rising from the floor than YAs: HOs took twice as long to rise (HO range 2.4–6.4 s, YA 1.4–3.1 s), while COs took two to three times as long as the HOs (CO range 6.4–15.5 s). While all YAs and HOs rose from every position, a subset of the COs were unable to rise from any position, 24 percent when attempting to rise without a support and 13 percent when attempting to rise with a support. COs were most likely to be successful when rising from a side-lying position while using furniture support. The more able COs, as well as the other groups, rose more quickly and admitted to least difficulty when rising from the all fours position.

IMPLICATIONS—The inability to rise from the floor is relatively common in congregate housing older adults. Based on the differences between groups in time to complete the rise, determining the differences in rise strategies, and the underlying biomechanical requirements of rising from different positions with or without a support would appear to be useful. These data may serve as the foundation for future interventions to improve the ability to rise from the floor.

RECENT PUBLICATIONS FROM THIS RESEARCH

Rising from the floor in older adults. Alexander NB, Ulbrich J, Raheja A, Channer D. J Am Geriatr Soc 1997;45:564–9.

[108] MINIMIZING FALLS IN THE ELDERLY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A831-2RA)*

PURPOSE—Almost one-third of all ambulatory people over the age of 65 and not in nursing homes fall each year. Such falls are a major source of serious injury, morbidity, and mortality in the elderly population. Even in cases that do not cause injury, the fall itself may result in an increased sense of fear, less independence, curtailed activity, and a higher morbidity rate associated with inactivity. In previous studies, peripheral neuropathy, decreased proprioception, increased reaction time, and decreased strength have all been independently associated with an increased risk of falling. In addition, separate, but related, research has shown that taping the ankle can improve reaction time and strength in young athletic subjects with a history of ankle sprain. The aim of the present study is to determine the efficacy of two different ankle wrapping techniques as interventions to falling.

METHODOLOGY—A commercially available elastic ankle wrap, and a common method of ankle taping were used on two different groups of elderly subjects: fallers (those who have fallen two or more times during the 6-mo period prior to testing) and nonfallers. The neuromuscular condition of the legs was evaluated for each subject prior to testing. This evaluation consisted of a nerve conduction study as well as a physical examination. Subjects performed a series of tests designed to allow measurement of physical parameters that have been correlated to falling, including:

1. amplitude and velocity of sway during quiet standing, with and without visual feedback;
2. amplitude and onset latency of muscle response to a rapid (standing) talar tilt;
3. amplitude and onset latency of muscle response to rapid (supine) dorsiflexion and plantarflexion;
4. proprioceptive response to slow (supine) dorsiflexion and plantarflexion;
5. torque generated across the ankle joint in response to rapid (supine) dorsiflexion and plantarflexion; and
6. functional reach.

Measures of sway were made, using a commercially available platform equipped with force transducers, designed to monitor center of pressure data. Muscle responses were measured for the gastroc, peroneus longus, anterior tibialis, and gluteus minimus muscles, and recorded through a series of four surface electrodes placed accordingly. Comparisons of the measured parameters were made among the ankle wrap, the tape, and a control group (no ankle support at all) to determine which of these wrapping techniques, if either, may act as an effective intervention to falling in the tested population.

PROGRESS—Thirty-nine subjects have been tested. The protocol was modified after testing the first, and again after testing the second. As such, these two were considered trial subjects and have therefore been excluded from the main testing groups. Of the remaining 37 subjects, there are 17 fallers and 20 nonfallers; all completed the entire testing procedure.

PRELIMINARY RESULTS—Preliminary analysis shows a greater incidence of nerve conduction studies abnormalities in the falling group when compared to the nonfallers. Although not unexpected, if this finding proves to be statistically significant it will be the first time it has been shown in a prospective fashion. Preliminary analysis also indicates that taping the ankle may improve measures of sway in fallers who have normal nerve conduction studies.

FUTURE PLANS—We plan on completing the analysis of all of our data. We expect to learn more about nerve function in fallers and the effect of nerve function on measures of balance. We plan on using the experimental and clinical data to design and test a low cost orthosis that more closely mimics the effects of tape and thus may help prevent falls.

[109] LONG-TERM EVALUATION OF MAXILLARY SINUS BONE GRAFTS WITH DENTAL IMPLANTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420*
(Project #A649-3RA)

PURPOSE—Dental implants can greatly improve oral function. However, many candidates for implants have resorbed too much bone to support maxillary implants. Our initial studies were designed to determine if autologous cortico/cancellous bone grafts from the ilium to the maxillary sinuses will mature (consolidate) and support titanium cylindrical implants, which will in turn support a fixed prosthesis that can withstand the masticatory forces of a similar prosthesis in the mandible. It is expected that this protocol will determine whether the bite force will be less than, remain the same, or improve over that documented in our prior study and if the bone density at implant/graft bone interface will be less than, equal to, or greater than at implant/native bone interface. Bone loss (height) at implant/bone interface will be measured.

METHODOLOGY—An attempt to recruit the 20 subjects who have completed the treatment protocol in our prior studies will be made. Each participating subject will have an axial computed tomography scan, from which bony dimensions, volume and density of the grafts will be measured using the Image Analysis Workstation at the UTHSCSA Dental School. These scans will be accomplished during the first and third years of the protocol. Periapical radiographs will be taken with standardized projection geometry method in the Longitudinal Radiographic Assessment clinic at UTHSCSA and analyzed with digital image analysis methods. Bite force will be determined utilizing a gnathodynamometer with bilateral cross-arch bite element with results recorded on an X-Y plotter and reported in pounds force.

PROGRESS—All 20 subjects were contacted; 18 agreed to take part in this 3-year protocol. Fifteen have finished their first year evaluations; the other three are scheduled.

RESULTS—No data have been analyzed.

FUTURE PLANS—We will finish the required measurements, start the evaluation of the data obtained, and present for publication.

[110] A STUDY OF POLICY BARRIERS IMPEDING USE OF ASSISTIVE TECHNOLOGY BY PERSONS AGING WITH DISABILITIES

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Sponsor: *Rehabilitation Research and Training Center on Aging with Disabilities, Rancho Los Amigos Medical Center, Downey, CA*

PURPOSE—The two primary objectives of the study are the investigation of the adequacy of current policies on AT for persons aging with or into disability and the identification of the need, if any, for policy changes. In addition, project staff are providing assistance in the analysis of consumer data on AT that will describe current patterns of AT use and recent changes in patterns of use; examine the impact of AT on health status and on quality of life issues; and identify the barriers, both attitudinal and financial, which may limit access to AT.

METHODOLOGY—Both state- and consumer-level policy research is being conducted drawing upon a variety of methods, including review of existing federal, state, and consumer-level policy reports and research; interviews with key informants; additional analyses of national survey data; and conducting additional project studies to identify consumer issues and investigate state policy efforts.

PROGRESS—Accomplishments to date include: 1) a nationwide survey of state rehabilitation agencies that will identify the extent to which state rehabilitation agencies are knowledgeable about the AT needs of, and serve as providers for, middle-aged and older adults; 2) a study of 10 State Units on Aging (SUAs) in states identified as having high levels of effort in AT and home modifications (HM); 3) a nationwide survey of state legislative analysts about a variety of state policies affecting AT; 4) an analysis of RESNA consumer data on adults age 40 and older to determine particular problem areas, unmet needs, types of problems encountered, and receipt of AT information and referral services; 5) an analysis of AT data from the 1990 National Health Interview Survey (NHIS) to examine the types and use of AT among older adults and identify barriers to access; and 6) an analysis of data from a study of SUA and State Tech Act Projects conducted in 1995 by the American Society on Aging.

RESULTS—State-level policy analyses indicate that much remains unknown about the AT activities of individual states. Some states do, however, stand out as leaders in the area of AT and a survey of aging agencies in exemplary states was conducted to gain an understanding of why this is the case. Preliminary consumer-level analyses suggest that significant changes in function occur over time among people aging with long-standing disabilities and that AT needs change correspondingly. Additional analyses are planned to identify barriers to use of and access to AT.

FUTURE PLANS—Three studies will be completed during 1997/98. First, analyses are underway using data from the survey “Changing Needs and Life Circumstances of Persons Aging with Disabilities.'' Our section of the survey focuses on policy relevant issues including information-seeking related to acquisition of AT; use and abandonment of devices; funding patterns; changing needs over time, and unmet needs for AT. Approximately 350 surveys have been completed. Second, data from the national ''Survey of State Rehabilitation Agencies'' have been collected. Analyses are underway to examine AT issues including agency policies, interagency networks, state initiated AT policies and programs, agency decisionmaking, budget allocations affecting provision of AT, and organizational structures. Third, data from a survey of 10 SUAs in states identified for their exemplary efforts in the area of AT/HM are being analyzed to gain insight into efforts to meet the needs of older adults with disability.

RECENT PUBLICATIONS FROM THIS RESEARCH

Ageism, disability and access to environmental interventions. Liebig PS, Sheets DJ. Technol Disabil. In press.

The aging network and the home modification needs of elders. Sheets DJ, Emerman J, LaBuda D. Technol Disabil. In press.

[111] ACCESS TO PRODUCTS FOR CONTINUED INDEPENDENCE FOR ELDERLY AND DISABLED PERSONS

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Sponsor: *None listed*

PURPOSE—This project will develop and evaluate software programs called Intelligent Assistive Device Identifier (IADI), and Remote Computer Accessibility Assessment (RCAA).

The IADI is a self-description and activity limitation description program which allows a person or their caregiver to describe themselves in terms of their disabling conditions and/or the activities they wish to perform, but have difficulties accomplishing. The objectives of the system are to promote freedom of choice and independence, enabling people to define their own functional problems and be presented with a product listing from which to select assistive technology products for maximizing their independence; to provide information to the public to overcome the barriers of access to information about assistive devices and technology (AT); to provide information to health professionals that will save them time and enhance their ability to recommend the appropriate AT for specific and complex disabilities; and to provide information to public and private insurers to aid in their cost/benefit assessment procedures for AT coverage.

The second program, RCAA, will provide a specialized assessment protocol to determine computer input needs. The RCAA will guide the user through a series of ever more specific questions regarding the user's abilities, resulting in information and recommendations for input technologies.

PROGRESS—A consortium consisting of Baycrest Centre for Geriatric Care, University of Toronto, and Bloorview MacMillan Centre was established to seek commercial and other sponsors for this project.

VI. Head Trauma and Stroke

[112] IMPROVEMENTS IN A NEW TECHNIQUE FOR INCREASING MOVEMENT AFTER STROKE

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B1692-RA)*

PURPOSE—We seek to confirm our preliminary observations that the incapacitating motor deficit of many persons with stroke can be substantially reduced, and their functional independence greatly increased, through the use of techniques involving Constraint-Induction (CI) therapy. The CI techniques tested to date include restriction of movement of the unaffected upper extremity by a sling and training of the affected upper extremity for 2 wks. The main objective of this project will be to develop and test two modifications of this technique in an effort to improve its effectiveness for those suffering the chronic effects of stroke, whose functional independence has been significantly compromised by motor deficits.

METHODOLOGY—We shall test two modifications: first, we shall decrease the intervention time from the current 2 wks to 1 wk, to determine whether the procedure can be made more cost effective, and second, we shall apply the intervention to subjects with greater motor disability than have been worked with to date (an estimated 20 percent of the chronic stroke population with motor deficit), to determine whether it is possible to expand the number of those who can benefit from the therapy in the next lower functioning 40 percent of the population.

The research will be carried out with 80 chronic stroke subjects at the Birmingham VA Medical Center. Veterans will be identified by chart review and screened by telephone calls. Those found to be eligible will be asked to come to the clinic for informed consent and further testing. Those subjects meeting inclusion criteria will undergo a baseline battery of tests, including objective measures of motor function, ADL function, joint range of motion, and cognitive status. A self-report and caregiver report of ADL function will also be obtained. The number and severity of comorbidities will be assessed using the Comorbidity Damage Index of Charlson. Subjects will then be randomly assigned to one of the two groups to be studied in each of the two phases of the project.

In Phase 1, the results of 20 subjects given a 1-wk period of CI treatment will be compared with the results of 20 subjects in a comparison group given conventional physical therapy for 1 wk and the results already obtained from subjects given the 2-wk CI procedure. In Phase 2, the 2-wk CI procedure will be employed with two groups of 20 subjects each at the two lower levels of motor functioning (just below those we have tested until now), thereby obtaining CI therapeutic efficacy data for an estimated additional 40 percent of persons with motor deficit from chronic stroke effects. Treatment will be administered on an outpatient basis. Follow-up testing will be carried out at the end of each of the first 4 wks after the end of treatment and again 6 and 12 mo posttreatment. Follow-up testing will include measures of motor function and joint range of movement (at 6 and 12 mo posttreatment) and of ADL function (at each follow-up point).

PROGRESS—Ten control subjects have been tested who were given a general fitness placebo control intervention involving the same time period (2 weeks) and the same intensity of therapist-subject interaction (6 hr/day for 10 consecutive weekdays) as our previous subjects given CI Therapy. None of these subjects showed a significant improvement in upper extremity function. They, therefore, constitute a successful placebo control intervention. Ten more control subjects will be given the same intervention during the next year. Four lower functioning subjects who did not meet the project's former minimum motor criterion have been tested. Contrary to expectations, these subjects improved as much with CI Therapy as our previous higher functioning stroke patients. If these results hold up, it will indicate that CI Therapy is applicable to at least 50 percent of the chronic stroke population with motor deficit, and perhaps more—a much larger number than we previously thought would be amenable to therapy.

RECENT PUBLICATIONS FROM THIS RESEARCH

The arm motor ability test (AMAT): reliability, validity and sensitivity to change. Kopp B, Kunkel A, Flor H, et al. Arch Phys Med Rehabil 1997;78:615–20.

Constraint-induced (CI) movement therapy for motor recovery after stroke. Morris DM, Crago JE, DeLuca SC, Pidikiti RD, Taub E. Neurorehabilitation 1997;9:29–43.

Constraint-induced movement therapy: new approaches to outcome measurement in rehabilitation. Uswatte G, Taub E. In: Stuss DT, Winocur G, Robertson IH, editors. Cognitive neurorehabilitation: a comprehensive approach. Cambridge: Cambridge University Press. In press.

Perceptual correlates of use-dependent changes in cortical representation of the fingers in blind Braille readers. Sterr A, Mueller M, Elbert T, Taub E. Nature. In press.

Constraint-induction/forced use techniques to facilitate upper extremity use in stroke patients. Taub E, Wolf SL. Top Stroke Rehabil 1997;3:38–61.

Effects of motor restriction of an unimpaired upper extremity and training on improving functional tasks and altering, brain/behaviors. Taub E, Pidikiti RD, DeLuca SC, Crago JE. In: Toole J, editor. Imaging and neurologic rehabilitation. New York: Demos Publications; 1996. p. 133–54.

[113] LIMB MANIPULATION UNDER PATIENT CONTROL: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B1846-AP)*

PURPOSE—Stroke is the most common inpatient rehabilitation diagnosis, and its prevalence in DVA patients is increasing as aging WW II veterans join the population at highest risk. Upper limb paralysis is often resistant to therapeutic efforts. The resulting mobility and self-care impairments negatively impact discharge to the community and length of stay. Until significant gains take place in prevention of stroke and its sequelae, more effective methods are needed to maintain or restore the dexterity necessary for daily activities. This pilot study tested the concept and feasibility of a semiautomated therapy system for rehabilitation of post-stroke hemiplegia.

METHODOLOGY—We evaluated the utility of an electromechanical apparatus that allows patient control of passive or actively-assisted movements: the Mirror-Image Movement Enabler (MIME). Normally, this technique is implemented by a therapist who moves the paretic limb as the client either remains passive or actively attempts to contribute to the movement. We measured the external and subject-generated forces associated with programmed and self-directed movements during a simple tracking task and correlated these forces with the level of motor recovery of the subjects.

In programmed mode, pre-determined movements of the paretic arm were facilitated with the assistance, as necessary, of external forces applied by a small industrial robot. In the subject-controlled mode, movements of the nonaffected limb ipsilateral to site of cerebrovascular accident were sensed by position encoders, reflected symmetrically about the sagittal plane, and reproduced in the paretic limb with assistance of the robot. A six-axis transducer measured the assistive forces during movement, and optical sensors quantified motion.

PROGRESS—Six controls and 13 persons with hemiplegia participated in this pilot study.

PRELIMINARY RESULTS—MIME facilitated movement of one arm of each subject, both in programmed mode and in trajectories determined by voluntary contralateral arm movements. Performance of stroke subjects reflected their level of recovery. Overall, the more impaired subjects produced higher force values than less impaired subjects, but these forces were often misdirected relative to the direction of movement, and relative to the force directions when their contralateral limb performed the movements. There was a negative correlation between the force magnitude error vs. the FM score ($p<0.02$). We also observed performance differences between programmed and subject-controlled modes, with moderately to severely impaired subjects producing more effective forces over portions of the movement trajectories that were dependent on the control mode.

This pilot work demonstrated that patient-guided manipulation therapy of the paretic limb is feasible, and that forces measured by MIME correlate with the state of motor recovery, as measured by the Fugl-Meyer scale.

FUTURE PLANS—We propose to further study the use of assisted movement in recovery of upper limb function following stroke, investigating the utility of this technique in the very acute stages of stroke recovery, when the potential for a beneficial effect on functional outcomes may be even greater.

RECENT PUBLICATIONS FROM THIS RESEARCH

The use of a robotic device for post-stroke movement therapy. Lum PS, Burgar CG, Van der Loos HFM. Proceedings of the 1997 Conference on Rehabilitation Robotics, Bath, UK; 1997. p. 107–10.

[114] THE ROLE OF IMAGERY IN AUDITORY COMPREHENSION IN BRAIN-DAMAGED ADULTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C818-RA)*

PURPOSE—The purpose of this project is to examine the contribution of imagery as an aid to the auditory comprehension of connected language in individuals with aphasia and right-hemisphere lesions. Do imagery-laden verbal passages enhance accuracy of comprehension on verbal tasks? Do imagery-laden verbal passages increase inter- and intrahemispheric differences in persons with right and left brain-damage, as measured by probe auditory evoked potentials (AEP)?

METHODOLOGY—Using a signal-averaging program, a probe-evoked potential technique (in which a task-irrelevant sensory stimulus is superimposed on ongoing complex tasks) is used to measure intra/interhemispheric response to the task. The paradigm includes a baseline or nondifferentiating task and two language or left hemisphere tasks. The baseline task provides a comparative measurement of processing a task that has never been shown to differentially bias one hemisphere over the other. The two language tasks include passages rated as high imagery and passages rated as low imagery by normal subjects. In addition, multiple choice questions are asked following each language passage. These questions are used as measures of the subject's comprehension of the material as well as an indicator of his/her involvement in the task. The questions require both literal and interpretive conclusions to be made about the material. Persona with aphasia whose PICA Overall severity levels fall between 55th-85th percentile are included as subjects, and persons with right hemisphere damage, whose overall scores on the PICA fall between the 55-85th percentile, serve as pathological comparisons. In addition, a control group without brain damage is included. Each subject undergoes two sessions of electrophysiological testing resulting in evoked potential measures of hemispheric responsivity and test/retest data.

PROGRESS—All subjects have been completed. Data scoring and analysis is proceeding and will be completed in the next month.

FUTURE PLANS—Utilizing the results from the study, development of treatment paradigms that may be useful to the aphasic subjects will be selected and tried in the clinical setting.

[115] FACTORS AFFECTING TIME BETWEEN CVA ONSET AND REHABILITATION IN THE VA

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #E2108-PA)*

PURPOSE—According to data from the Uniform Data System for Medical Rehabilitation (UDSMR), a national rehabilitation patient database, the mean length of time between the day a patient has a stroke (CVA) and the day he is admitted to an inpatient rehabilitation unit is significantly longer in the VA healthcare system than in nonVA facilities. The reasons for this disparity are unknown. The objective of this project is to describe how rehabilitation onset-admission time for CVA patients in the VA varies with: patient social and medical characteristics, VA Medical Center facility policies and procedures, VA Medical Center external referral patterns, patient geographic distance from VA Medical Center, and patient data coding errors.

METHODOLOGY—This project is a retrospective review of persons with CVA discharged from 15 VA rehabilitation bed units in fiscal years 1995 and 1996, using both medical record information and the VA-UDSMR database. Only those admitted for their first inpatient rehabilitation for the current stroke were included; those re-admitted for the same stroke were excluded. Also excluded were persons with rehabilitation onset-admissions time greater then 365 days (n=34) or who were missing critical dates precluding the determination of onset time (n=16). The VA-UDSMR database includes patient demographic information such as date of birth, zip/postal code, living setting prior to admission, marital status, rehabilitation diagnosis, admission and discharge dates, and date of disability onset as well as functional status at admission and discharge. The medical record review of individual cases will add information regarding coding errors (CVA vs. other rehabilitation diagnoses, or new admission vs. readmission), comorbidities, and complications during the acute period of hospitalization, and a decomposition of rehabilitation onset-admission times into smaller units of time (i.e., initial referral, diagnostic consult, subsequent referral).

Data from the study sites will be incorporated into a single database and analyzed. The effect of coding errors, social, and medical characteristics will be examined using parametric (ANOVA), and nonparametric (Kruskali-Willis) tests. Linear regression will be used to examine the effect of multiple covariates (e.g., geographic distance) on rehabilitation onset-admission time. The influence of facility processes/procedure and referral pattern variables on rehabilitation onset-admission time will be examined using multivariate regression techniques.

PROGRESS—Demographic and functional data on 1045 new CVA cases admitted to the study sites during FY 1995 and FY 1996 has been extracted from the VA-UDSMR database; from this, a sample of 300 cases has been randomly identified for medical record review (20 cases per site). To date, data abstraction from medical records has been successfully completed at 5 sites and site visits have been scheduled at the remaining 9 facilities.

PRELIMINARY RESULTS—Of the 1045 new CVA cases, 98 percent were male and 51 percent were married at the time at the time of admission; 590 (56 percent) were admitted to rehabilitation from an acute unit within the same facility, 221 (21 percent) from an acute unit in another facility, and 182 (17 percent) from home. The remaining 52 (6 percent) were admitted from a variety of long-term care settings. Those admitted from an acute unit within the same facility had a onset time (mean (1SD)) of 25.4 (39.9) days. Onset-admission time for those admitted from other acute facilities was 34 (33.7) days, for those admitted from home, 51 (73.5) days, and for those admitted from long-term care settings, 73 (67.8) days. Though preliminary, these data suggest that the location from which persons are admitted plays a role in the length of time it takes to transfer them into rehabilitation settings.

[116] CORTICAL CONTRIBUTIONS TO THE RECOVERY OF MOTOR FUNCTION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B2013-RA)*

PURPOSE—The purpose of this project is to determine which brain areas contribute to the recovery of wrist movements after damage to the primary motor cortex in monkeys.

METHODOLOGY—The experiments use functional imaging of the brain with ^{14}C 2-deoxyglucose (2-DG) to define the pattern of cortical activation in normal monkeys when they perform step-tracking movements of the wrist. The same technique is used to define the pattern of cortical activation in monkeys that have recovered the ability to perform step-tracking movements of the wrist after removal of the arm area of primary motor cortex.

PROGRESS—We have examined the deficits in wrist movement and muscle activity in 2 monkeys after removal of the arm area of primary motor cortex. We have applied the 2-DG technique in these monkeys to determine which brain areas have increased metabolic activity during step-tracking movements of the wrist.

PRELIMINARY RESULTS—Preliminary analysis of brain tissue from one of the animals suggests that 2-DG uptake is elevated in some of the premotor areas in the same hemisphere as that receiving damage to the primary motor cortex. On the other hand, activation in the opposite hemisphere does not appear to be higher than that of normal animals. These preliminary observations suggest that recovery of motor function following damage to the primary motor cortex depends on the increased involvement of the premotor areas in the generation and control of movement.

IMPLICATIONS—Our data should enable clinicians to make more accurate predictions about the potential for and time course of functional recovery after a cortical stroke. Specifically, our studies should indicate which cortical areas are essential to the recovery of wrist movements following damage to the primary motor cortex. The potential for recovery may be good if these areas are not involved in the disease process and may be limited if these areas are involved.

[117] N-ACETYLASPARTATE: A PREDICTOR OF OUTCOME IN NEUROREHABILITATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B785-RA)*

No report was received for this issue.

[118] CULTURAL INFLUENCE ON APHASIA IN AFRICAN-AMERICANS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C888-2RA)*

PURPOSE—In this investigation we seek to determine whether traditional aphasia tests are culturally biased and to develop culturally appropriate measures for aphasia through answers to two research questions: Does performance by neurologically normal African-Americans differ from performance by neurologically normal Caucasian-Americans on traditional aphasia tests, culturally appropriate discourse measures, and culturally appropriate communication profiles? Are there differences in the severity and profile of language deficits between aphasic African-Americans and aphasic Caucasian-Americans on traditional aphasia tests, culturally appropriate discourse measures, and culturally appropriate communication profiles?

METHODOLOGY—Study participants will be 35 nonimpaired African-Americans; 35 nonimpaired Caucasian-Americans; 35 aphasic African-Americans; and 35 aphasic Caucasian-Americans. Nonimpaired subjects will have no history of neurological impairment. Aphasic subjects will be aphasic subsequent to a left hemisphere cerebral vascular accident and at least 3 mo post-onset. Two aphasia tests, the Western Aphasia Battery and the Token Test from the Neurosensory Center Comprehensive Examination for Aphasia, a discourse battery that includes four culturally appropriate tasks designed to elicit narrative discourse, and two functional communication profiles that rate communication competence in a variety of functional communication activities, will be administered to all subjects. To answer the primary research questions, analyses of variance and covariance and Chi Square analyses will be used to compare normal African- and Caucasian-Americans and aphasic African- and Caucasian-Americans on the traditional aphasia tests, discourse measures, and communication profiles.

PROGRESS—Discourse stimuli and tasks have been developed and pilot-tested for validity and reliability. Study participants are being recruited and evaluated.

[119] A CONTROLLED STUDY OF THE EFFECTS OF EMG FEEDBACK AND ELECTRICAL STIMULATION ON MOTOR RECOVERY IN ACUTE STROKE PATIENTS

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

PURPOSE—Despite conventional rehabilitation efforts, loss of upper extremity control continues to be one of the main limiting factors determining functional independence in stroke survivors. The restoration of motor control relies on the convergence of at least three types of physiologic information: central representations of motor output encoding the goal of movement, afferent input to provide the means to monitor movement progress, and relevant data from motor memory.

METHODOLOGY—Technical difficulties that hampered subject testing early in the project have been resolved. Although staff turnover is a concern, as the project involves 10 occupational therapists, the core group has remained intact and training of additional therapists is an ongoing process. Subject recruitment has been difficult with the decrease in the length of stay for stroke rehabilitation patients. We need 4 wks to complete the treatment sessions and the average length of stay is now 22 days.

PROGRESS—Despite these limitations, randomization has continued with the low-motor patient group. Currently 36 stroke survivors with low motor function have been randomized; 27 have completed 8 to 20 treatment sessions; 9 patients did not complete treatment because of equipment failure (3), short length of stay (3), fatigue (1), and lack of tolerance to the electrical stimulation (2); and 15 have completed the 1-yr follow-up evaluation and final evaluations will be completed over next 6 mo. A database is being established for data analysis.

[120] EFFECTS OF AEROBIC EXERCISE ON YOUNG PERSONS POST-STROKE

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

PURPOSE—Young stroke survivors participated in an aerobic fitness program to determine the effects of aerobic exercise on fitness levels, ambulatory speed, and life satisfaction.

METHODOLOGY—A pre-post design was used to allow each subject to act as his/her own control. The first 10-wk session was the initial control period. Subject were instructed to maintain the same activity level. The aerobic walking program was introduced at the onset of the second 10-wk period. Subjects ambulated three times per week for a minimum of 20 min at their target heart rate (HR) with a warm-up and cool-down phase included in each session. Participants' blood pressure and HR were taken at the beginning and completion of each exercise session to ensure a return to baseline measures. HR and rating of perceived exertion were used to monitor subjects during baseline. An educational component was provided on a weekly basis; topics discussed were relevant to stroke rehabilitation and exercise. The final 10 wks served a the second control period, During this interval, subjects were encouraged to continue with independent exercise as performed during the previous structured walking program. Local health clubs were visited by the authors to form a liaison between community-based facilities and any interested participants, and to ensure that the specific needs of stroke survivors would be sufficiently addressed. Community reentry is an important facet that was promoted through an ongoing emphasis on safe, independent exercise for the participants throughout the study.

Sub-maximal treadmill tests were performed at the onset of participation in the study, after the first control period, after the completion of the aerobic walking program, and at the end of the second control session (At 0, 10, 20, and 30 wks).

PROGRESS—Ten subjects, 7 men and 3 women, ages 29–62 years (mean=49), were able to finish the entire protocol. Due to the length of the study (30 weeks), a number of subjects had to discontinue participation because of schedule conflicts, including return to work or school, or transportation difficulties. The initial stress test using the treadmill produced abnormal results in several cases, necessitating a return to their primary physician for further evaluation and exclusion from data collection. The stress tests themselves proved difficult with some subjects due to gait deviations and fear while using the treadmill.

Eight of the 10 subjects demonstrated an improvement determined to be statistically significant at a t value of 3.98 in life satisfaction between the pre-test and post-test 2 as measured by the Quality of Life Index,

[121] PREVENTION OF THROMBOEMBOLISM IN STROKE REHABILITATION PATIENTS

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PURPOSE—Deep vein thrombosis and pulmonary embolism are important causes of morbidity and mortality in patients who have survived a recent stroke. Complicating the efforts of rehabilitation is a vulnerability to thromboembolism, which has been shown to affect 60–75 percent of elderly stroke patients. This is a study to compare two methods of thromboprophylaxis, calf compression boots (CC) and low molecular weight heparin (LWH), to see which is most safe and effective. The end points will be to determine efficacy as the presence or absence of thrombus, as defined by venous flow studies, venography, positive V/Q scan, or pulmonary angiography. Also, to determine the safety by the presence or absence of bleeding, either intracranial (positive CT scan or MRI), or elsewhere (decline in hematocrit of >5 percent, hemoglobin >2g).

METHODOLOGY—To date, 69 subjects have entered the study; of these, 55 have completed the study protocol. Forty-nine subjects had normal venograms and five had positive venograms indicating the presence of thrombi. Four of the positive venograms were in the LWH group and one was in the CC group. One subject in the LWH group has had bleeding. Subject recruitment is ongoing, with the goal of recruting a total of 100 subjects.

Fourteen subjects did not complete the protocol for the following reasons: one had gastrointestinal bleeding (LWH group); one an infection in leg that precluded use of CC; one was a scheduling error; and one withdrew from the study (or was withdrawn by the family). In the remaining six subjects, attempts at venography were unsucessful, but there was no clincial or ultrasound evidence of thrombi.

PROGRESS—Summary of data collection at this point is as follows: None of the 69 subjects exhibited clinical evidence of thrombosis; 5/55 or 9.1 percent showed venographic evidence of thrombosis; one subject from each group had adverse events in the trial; and both methods of prophylaxis are safe and effective. The numbers are still insufficient to conclude that one intervention is superior to the other. Data collection and analyses are continuing without change in the protocol or methods.

RECENT PUBLICATIONS FROM THIS RESEARCH

New pharmaceutical agents in antithrombotic therapy. Green D. In: Yao JST, Pearce WH, editors. Progress in vascular surgery. Stamford, CT: Appleton & Lange; 1997. p. 51–9.

Complication avoidance: deep venous thrombosis and pulmonary embolism. Englehard HH, Cozzens JW, Green D. Perspect Neurol Surg 1996;7:133–48.

[122] THE EFFECTIVENESS OF A TELEPHONE SUPPORT GROUP FOR STROKE CAREGIVERS

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

PURPOSE—The study explores the effectiveness of a unique intervention for the stress of older spousal caregivers of stroke survivors. One hundred thirty-six caregivers, 60 yrs of age and older, of spouses with stroke are randomly assigned to a treatment or control group. The treatment group participates in an 8-wk professionally led educational/support group held by telephone conference calls. They are assessed upon recruitment, after the group intervention, and at 6 mo. The control group receives written material on caregiver stress and is assessed upon recruitment and after 6 mo. At the end of their control group commitment, they are entered into the treatment group, participate in a support group, and are followed for an additional 6 mo. The study hypotheses are that the treatment group shows less depression, loneliness, burden, increased health behaviors, and increased competence. The research protocol has also been revised to make the control group into a ''wait list'' control. In this design, control subjects go on to participate in the treatment group after completing the control condition.

METHODOLOGY—There have been no substantive changes to the study protocol during the last year. The wait list control design change executed last year has been working well in maximizing the participation of subjects and assuring that they all have opportunity to be involved in the treatment program.

All strategies for subject recruitment developed to date have continued. These include identification of eligible family members through admissions at two hospitals, newspaper articles, newsletter advertisements, circulation of flyers, and mailings with follow-up calls. Recently, the research team has been successful in obtaining a public service announcement, a short spot on a radio health program, and a TV spot on a local news program is currently being completed. These media programs have highlighted the stress of coping for a stroke survivor, and so they have also addressed the RRTC-Stroke mission of community education.

PROGRESS—A total of 122 subjects have been recruited with 10 subjects dropping out before the initial assessment. Dropouts after initial assessment and full enrollment in the study equal 28, resulting in a dropout rate of 23 percent. Current study enrollment is 84 subjects. The most frequent reasons for dropping out include: no need for a support group, spouse deceased ending their eligibility, and subject lost to follow-up. There are 40 subjects in the treatment group (33 completed) and 44 in the control group (34 completed). The research team is currently beginning the twelfth support group. It is anticipated that recruitment will end in Summer 1997 and that the last subjects will complete the study by the end of Spring 1998.

RESULTS—The most recent sample of subjects analyzed consisted of 87 spousal stroke caregivers, average age 69.7 years (SD=6.8). The majority are women (76 percent), white (74 percent), well educated (M=14.4 yrs, SD=2.7), and in long-standing marital relationships (M=41.7 yrs, SD=12.8). They have been providing care in the home for an average of 2.9 yrs (SD=4.0; M=1.5; range=1 mo–27 yrs).

The reliability and validity of the 17 item Measure of Caregiver Health was evaluated with Rasch Analysis

(Rating Scale Analysis), a psychometric procedure that transforms raw summed scores to a linear (interval-level) measure and evaluates the extent to which items cohere to define a unidimensional construct. With the elimination of 1 poorly fitting item and recalibration of the scale of several others, the 16 remaining items defined a coherent measure of health with good item reliability (0.94). The overall health of caregivers was skewed in a positive direction with 80 percent of the sample reporting good to excellent health. However, 31 percent of subjects indicated substantial symptoms of depression. Thirty-six percent reported one or more unintentional injuries in the last 6 mo with about half of these attributing them to the stress of caregiving. Chi-square analyses showed that subjects reporting injuries were more likely to indicate use of medications for sleep, more days when they were too ill to care for their spouse, greater stress and poorer self-care in the last 6 mo ($p<0.05$) than those without report of injury. A revised measure of health was derived by eliminating the items pertaining to injury to avoid confounding the evaluation of the relationship between injury and health. Multivariate analysis of variance with multiple dependent variables (health, depression, burden, and stress) indicated a significant effect for groups (no injuries/injuries) ($p<0.001$); post-hoc analyses showed poorer health, greater depression and higher burden ($p<0.001$) in caregivers who reported injury. A second multivariate analysis of variance was completed for the same dependent variables but with the independent variable defined as 1) no injury, 2) injury not attributed to caregiver stress, and 3) injury attributed to caregiver stress. A significant difference across these three groups was found ($p<0.001$); post-hoc analyses showed that the caregivers attributing injury to caregiver stress reported the poorest health ($p<0.002$) and highest burden ($p=0.001$).

This preliminary analysis indicates that a coherent measure of caregiver health was developed which incorporates perceptions of health and self-care with report on the frequency of specific health- and illness-related behaviors. While the majority of the spousal caregivers indicated good health, engaged in health promoting activities and handled stress adequately, a substantial subgroup reported distress and occurrence of unintentional injury. A relationship between injury and both poor physical and emotional health was found.

[123] COURSE OF RECOVERY OF COGNITIVE-COMMUNICATIVE PROBLEMS IN RIGHT-BRAIN-DAMAGED INDIVIDUALS

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PURPOSE—Historically, it was assumed that only left hemisphere (LH) damage resulted in language deficits while right hemisphere (RH) damage had no important effect on communication. However, recent evidence suggests that the RH makes an important contribution to language processing and it is now widely acknowledged that RH stroke also results in impairments in communication. RH communication impairments are believed to result from underlying deficits in attention, memory, and perception. However, the precise relationship between communication impairment and deficits in these cognitive processes is not well understood. Appropriate rehabilitation interventions cannot be designed until a better understanding of the relationship between communication and these cognitive processes emerges. There also are very little data regarding the course of recovery of cognitive-communicative problems in persons with RH damage. Increased knowledge about the rate, amount, and patterns of recovery of communication problems in them is needed to facilitate the selection of more effective rehabilitation interventions.

METHODOLOGY—Subject recruitment has been progressing slowly but steadily. The charts of all consecutive admissions to RIC with unilateral RH stroke are reviewed weekly. This year, 13 new subjects have been recruited and have participated in the initial evaluation session. This brings our total number of subjects to 51.

Seven of these subjects have been followed longitudinally over 18 mo and have now completed their 4 test sessions; 8 have been tested 3 times; and 13 subjects have been tested twice. Most of the repeated evaluations have been conducted in the current reporting period.

PROGRESS—Data analysis is underway. All cognitive tests have been scored and the discourse of all subjects has been transcribed. Preliminary analyses have focused on the changes in unilateral visual neglect over time; the relationship between unilateral visual neglect and production of informational content in a story retelling task; and on performance trends on word list recall and recognition, both in the acute stage and longitudinally over time. Additional analyses are now completed on 30 subjects; these have continued to support our findings documented last year on 20 subjects.

With regard to unilateral hemispatial neglect, results indicate that there is a relationship between production of meaningful content and performance on a test of unilateral visual neglect. Furthermore, subjects with persistent hemineglect (over a period of at least 1 yr) produced less meaningful content than subjects with a transient neglect (i.e., no neglect evident at 6 mo postonset). These findings are consistent with the objectives of the study.

With regard to word list recall and recognition, results indicate that poor performance is associated with difficulties in the encoding process rather than in the retrieval process; therefore, individuals in a rehabilitation program would benefit from practice, repetition of important information, and the imposition of a strategy that facilitates encoding. The precise relationship between performance on this task and production of meaningful discourse is yet to be examined.

RECENT PUBLICATIONS FROM THIS RESEARCH

Information content and unilateral neglect: a longitudinal investigation of five subjects with right hemisphere damage. Cherney LR, Drimmer DP, Halper AS. Aphasiology 1997;4(5):351–61.

[124] REDUCING MOTOR DISABILITY IN HEMIPARETIC STROKE BY MANIPULATION OF SENSORY INPUT FROM THE PARETIC UPPER LIMB: A QUANTITATIVE EVALUATION

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PURPOSE—The disability of the upper limb after a hemiparetic stroke is often perceived as one of their most frustrating experiences by stroke survivors. There are well-defined reasons for the disproportionate impact of cerebral stroke in upper limb function, such as the greater relative area of cortex devoted to upper limb control, coupled with the fact that arm motions play a major role in both activities of daily living and in the workplace. A large number of neurotherapeutic techniques claim that the effect of their respective interventions creates the best results. However, because of the absence of quantitative measures to evaluate the effect of these therapeutic interventions on limb motor behavior, little progress toward the determination of the optimum intervention protocols for impaired limb motion has been made. The broad objective of our research is to quantify how sensory input can reduce disturbed muscle synergic relations and/or spasticity and thereby improve function of the impaired limb.

We are manipulating cutaneous afferents with a mixture of Lidocaine and Prilocaine (EMLA) to observe the effects on abnormal muscle synergies following stroke on control subjects to determine the analgesic effect on various cutaneous afferent types. We investigated the ability of EMLA to selectively block specific sensory modalities as a function of time. This information would contribute to ongoing research in spasticity reduction using manipulation of cutaneous afferent activity in stroke patients. EMLA is a commercially available topical anesthetic cream which is known to produce complete anesthesia to venupuncture. However, the effects of EMLA (or any topical anesthetic) on other sensory modalities has not been investigated. We have sought to further characterize the effects of EMLA on light touch, pain, cold, heat, and vibration (30 and 130 Hz). These sensations are carried by different fiber types: light touch and vibration by A fibers, pain by A and C fibers, cold by A fibers, and warm by C fibers.

METHODOLOGY—This study was performed on a group of nonimpaired controls (n=32, 20 females, 12 males, ages 22–55) with negative medical histories. Following baseline testing, 2 g of EMLA was applied to a 3 cm diameter circle of skin over the biceps bilaterally. One application was removed after 15 min. Starting with the time of removal, the subjects were blindfolded and the application site was tested every 10 min. The contralateral application remained in place for 60 min and was tested once after removal of the cream. Light touch was tested using Von Frey hairs, pain through pin prick, cold using a 1.4 cm diameter metal weight at 0 °C, heat using a 1.8 cm diameter metal weight at 44 °C, and vibration using a motorized device with an 8.0 mm diameter surface at frequencies of both 30 and 130 Hz. The data for each sensory modality were collapsed to 'no change,' 'diminished,' or 'absent.' These descriptors were assigned ordinal values for statistical analysis. Data for heat and vibration were excluded due to confounding factors present in the testing procedure. Regression lines were fit to the group data for cold, pain, and light touch plotted as percent of population with absent sensation as a function of time. A two-factor (time and sensory modality) ANOVA was performed on the group data to determine if there were significant differences ($p<0.05$) in the rate of loss between modalities.

PROGRESS—Significant differences in this rate of loss were found for the 15-min application protocol. Post-hoc tests showed significant differences between cold and light touch, and pain and light touch ($p<0.05$). No difference was found between pain and cold. In addition, extrapolation of the regression suggested that the earliest absence of sensation from time of application of the anesthetic was 8 min for pain, 9 min for cold, and 20 min for light touch. These results suggest that EMLA affects Ad and C fibers at a faster rate than Ab fibers. This implies that a topically applied anesthetic affects nerve fibers in a manner similar to perineural anesthetic injection as found in previous studies.

The ability to selectively block different afferent fibers over time will permit the investigation of the effect of different afferent feedback on spasticity and abnormal torque synergies. We are currently testing EMLA on a group of stroke survivors (n=10) for repeatability of the findings. To date we have seen four subjects, and data analysis is ongoing, along with data collection on the remaining six. If we obtain consistent results in the stroke group, initiation of a spasticity reduction protocol using EMLA will be initiated.

[125] THE PREDICTIVE VALUE OF COGNITIVE/BEHAVIORAL MEASURES IN PATIENTS AFTER STROKE IN ASSESSING FUNCTIONAL OUTCOME

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

PURPOSE—The major objective of this study is to examine the efficacy of neurological tests in predicting functional outcome for persons with stroke. A battery of neuropsychological tests will be administered to each subject early post-stroke. Functional outcome will be measured at 1, 6, and 12 mo post-stroke. Analyses will be done to determine the critical variable or set of variables related to functional outcome.

METHODOLOGY—In Fall 1995, we were approved by the IRB to modify the enrollment criteria. Previously we had to exclude a large number of subjects because they had a history of substance abuse or had a previous stroke. We felt that allowing subjects with such a history into the study would not significantly interfere with our ability to attribute observed cognitive deficits to strokes. By allowing more subjects into the study, we will increase our predictive power. Moreover, by liberalizing our enrollment criteria, we improve our external validity in that our sample will more closely resemble the actual population seen in clinical settings.

The rate of enrollment of subjects increased after the inclusion criteria was modified with almost twice as many subject enrolled per month. A total of 170 subjects have been enrolled and tested.

PROGRESS—As expected, we are finding substantial variability among subjects in their ability to complete the different tests in the neuropsychological battery. Deficits in motor function, vision, and receptive language ability appear to have a strong effect on test completion. One of our goals is to determine which tests can still be used when these functional limitations exist. A review of the first 58 subjects in our database show completion rates ranging from 50 subjects able to complete the Benton Facial Recognition Test to only 9 subjects able to complete the Tower of Toronto. Further data collection and analysis will take place in the next year.

[126] IMPROVING VOCATIONAL OUTCOMES OF INDIVIDUALS WHO HAVE SUSTAINED A STROKE

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Sponsor: *Department of Education, National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

PURPOSE—The overriding goal of Vocational Rehabilitation (VR) is to assist individuals with a disability to return to work at a level appropriate to their abilities. The vocational functioning and status of individuals who have sustained a stroke is significantly less than individuals with other disabling conditions. It is strongly felt that there currently exists a lack of a focused, succinct assessment to assist the VR professional in providing cost-effective, high quality services to increase successful vocational outcomes.

The broad objective of this project is to develop a good assessment tool for proper diagnosis for VR and improve the probability of positive vocational outcomes for stroke survivors. Specific objectives of this study are to investigate the Functional Assessment Inventory (FAI) for its suitability for application to the stroke population and to identify appropriate areas of the FAI that require modifications to improve the assessment tool for that population.

PROGRESS—As of May 1996, all of the data collection and data entry for the 110 nonexperimental cases have been completed. A total of 100 cases in the experimental group have had the modified FAI administered. Data analysis on 88 of this 100 found the experimental and the nonexperimental groups to be similar in areas such as gender and race. The experimental group has slightly more subjects with aphasia. The nonexperimental group has more individuals who have completed college and were employed in professional occupations before their stroke.

Data analysis also found the average FAI total scores differ by 10 points between the Employed Group (EG) and the Not Able to Work Group (NG) at case closure. The NG included those placed in sheltered workshops, volunteer positions, and retirement. Those who could not be placed but were continuing in training had an intermediate score. Based on this preliminary analysis, it seems that the FAI is helpful for predicting the probability of vocational outcome for these individuals. It appears that this will serve as a valuable tool for assessing vocational outcomes and planning vocational rehabilitation services for the stroke population. The group receiving the FAI had a shorter length of time from intake to case closure than the nonexperimental group. In addition, the group receiving the FAI required a lower number of units of vocational rehabilitation services. It appears that using the FAI did facilitate identifying the direction for vocational planning and therefore resulted in greater cost effectiveness.

[127] COMPUTER SIMULATION ANALYSIS OF COORDINATION DEFICITS IN POST-STROKE HEMIPLEGIA

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PURPOSE—Computer models of the musculoskeletal system now make it possible to study the motor control of multijoint movements in terms of the mechanical requirements needed to accomplish particular tasks. One of the next great challenges in biomedical engineering will be to apply this technique to help restore function to people with disabilities. It is to be expected that these models will be powerful tools for pinpointing the mechanical implications of central and peripheral nervous system deficits, for designing more effective surgical interventions, and for devising rehabilitation strategies that allow the patient to make optimum use of the function that still remains.

The focus of our research is to use computer models in conjunction with experiments to investigate deficits in the neural control of the legs in persons with post-stroke hemiplegia, a group that constitutes a sizable and growing portion of the rehabilitation population. Rehabilitation strategies that were more effective at improving their ability to walk would dramatically improve their quality of life.

METHODOLOGY—We believe that the deficits of these persons can be studied effectively using a servomotor-assisted ergometer-pedaling paradigm we have developed in the course of ongoing research. Since pedaling is a constrained movement, its biomechanics can be modeled in a straightforward fashion. However, pedaling is still complex enough to be extremely interesting from a motor control point of view. Like most leg functions, pedaling and walking can be characterized by the activation of multiple muscles to produce a force that is transmitted through the foot to the environment. All the major functions required for successful interaction with the environment can be accomplished on a servomotor-assisted ergometer, including generating isometric force, and performing positive and negative mechanical work. Furthermore, these functions can be decoupled from functions in the nonplegic leg, through use of the servomotor-assisted ergometer. Depending on the mechanics of the endpoint/environment interaction, a similar activation of muscles could result in an isometric endpoint force, mechanical work being done by the leg (positive work), or mechanical work being done on the leg by the environment (negative work).

Specifically, we propose to use a servomotor-assisted ergometer pedaling paradigm to test the hypothesis that nervous system constraints (inappropriate synergies and interlimb coupling) limit the ability of the hemiplegic person to generate the appropriate endpoint force for a desired function. In order to test this hypothesis, we propose to develop a 3-D computer simulation model of the musculoskeletal system and the pedalling task to study the inter- and intra-leg coordination responsible for producing endpoint forces to interact with different mechanical loads. With that model, we shall attempt to determine how ‘‘neural constraints’’ limit the ability of the person with hemiplegia to generate isometric force in a desired direction, to do mechanical work in a desired direction during discrete tasks, and to do mechanical work during cyclical tasks.

PROGRESS—Pilot data have been collected on three subjects during static positions and during pedaling. Marker arrays were attached to all segments to determine 3-D orientation. The data are still being analyzed, but preliminary analysis suggests that the tested configuration of markers was successful for determining 3-D orientation of segments and can be adopted in the experiments. Necessary instrumentation has also been built.

VII. Independent Living Aids

A. General

[128] REMOTE REHABILITATION SERVICES NETWORK

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PURPOSE—This project will establish and evaluate a multimedia rehabilitation consultation network to allow clients and staff of remote Children's Treatment Centres and other rural community sites to share solutions and to consult with colleagues and professionals using multimedia telecommunication technology. The delivery of specialized services to rural or remote areas can be difficult, due to the large distances from specialized research and development facilities. The use of a telecommunications medium that incorporates two-way voice, video, and computer networking has tremendous potential to enhance services and reduce loss of work time for parents, school-time for clients, and travel costs for clients, parents, or professionals.

PROGRESS—In the first year of the Remote Rehabilitation Services Network (RRSNet) project, we carried out a survey of clinicians at Children's Treatment Centres in Ontario and at Bloorview MacMillan Centre to determine their needs for televideo technology; selected two sites in Northern Ontario (Laurentian Hospital in Sudbury and George Geoffrey's Children Treatment Centre in Thunder Bay) and one general rehabilitation Centre in Southern Ontario (K-W Ability Centre); actively promoted the concept of using televideo technology to provide or obtain (re)habilitation services within Bloorview MacMillan Centre and in children's rehabilitation centres in the province; and performed a thorough review of the literature and internet to determine the state of the art in the field of remote (re)habilitation services and to establish methods and applications of teletechnology.

FUTURE PLANS—From our limited experiences with the large-screen videoconferencing or group system, it is clear that a number of current rehabilitation services and educational activities could be carried out using this technology. So far, the applications selected appear to remain very close to the activities professionals have been doing all along. Face-to-face meetings have become screen-to-screen meetings. The challenge for the next few years will be to realize the added value of the information and knowledge tools that can now be made available to clients and clinicians. We believe that it is possible to use this technology as a catalyst for an entirely new and more efficient means of service delivery.

[129] THE AUSMAP DATABASE: CUSTOMIZING MINSPEAK VOCABULARY FOR AUSTRALIAN USE

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PURPOSE—The AusMAP database is a computer-based tool for storing, organizing, and printing vocabulary for users of Minspeak-based communication devices. AusMAP is particularly focused on vocabulary customized to suit Australian Minspeak users.

Minspeak-based communication devices have been used extensively with clients of The Crippled Children's Association (CCA) since 1993. During that time therapists have produced customized Australian versions of the IEP+ (called AusIEP) and, more recently, the UNITY Minspeak Application Programs (MAPs). As a result of the significant changes being made to the original MAPs, a need arose for professionally designed database in which the new vocabulary sequences could be recorded and printed out. The AusMAP database system is our response to that need.

METHODOLOGY—A formal specification was developed for the software tool with the following key features: a) A complete, user-friendly recording system of the AusIEP and AusUNITY vocabulary; b) the ability to selectively choose and print vocabulary and icon sequences in a range of sizes and layouts; c) the ability to store vocabulary specific to certain users; d) storage of multiple rationales, allowing choice of the most appropriate one for the client; e) the ability to add, delete, and edit the vocabulary; and f) the flexibility to run on a stand-alone computer without expensive additions.

PROGRESS—We have produced an initial version of the AusMAP database and are testing it. The software is centered around a large table of words/phrases and their corresponding Minspeak icon sequences. Each entry also allows storage of one or more rationales, one or more theme tags and one or more user tags. A theme tag is any word or short phrase denoting a distinguishing characteristic of a group of dictionary entries (e.g., "food," "sport," and so forth). It is also these tags that distinguish whether a vocabulary entry belongs to the AusIEP, AusUNITY, or other customized dictionary. A user tag is a name identifying a certain Minspeak user or group of users. User tags are a flexible scheme designed to link certain vocabulary to specific users. Besides this core dictionary, the software includes extensive facilities for extracting and printing subsets of the dictionary in the form of reports, dictionary listings, or therapy worksheets.

RESULTS—Although only in the initial stages of use, the AusMAP database has been seen to be a vast improvement over previous means of recording and organizing Minspeak vocabulary customized for Australian use.

FUTURE PLANS—The AusMAP database will be used by therapists and assistants of the CCA Speech Pathology Department, as well as by educators and families for the development of customized dictionaries, and the production of therapy and educational material. It is envisioned that clients in remote country areas will also have access to a version of the software, enabling more independent ownership of therapy programs by local therapists and teachers, with some support from the CCA.

RECENT PUBLICATIONS FROM THIS RESEARCH

The AusMAP database. Customising Minspeak Vocabulary for Australian Use. Stapleton D, Garrett R, Faulks J. Proceedings of the 3rd Australian Conference on Technology for People with Disabilities; 1997, Canberra, Australia. Regency Park, SA: The Regency Park Centre. In press.

[130] DAILY: MAKES DAILY LIFE EASIER

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Sponsor: *European Commission, Telematics Applications Programme, Sector Disabled and Elderly, and the participating facilities*

PURPOSE—The aim of the project is to develop a multimedia application (DAILY) that supplies information about assistive devices to elderly people with minor motor impairments who want to continue managing daily activities on their own. DAILY will provide knowledge about which assistive devices exist, enabling the individual to take the initiative in defining his or her own needs, solving problems, and placing appropriate demands on the responsible institutions and agencies in society.

METHODOLOGY—DAILY is a computer program that gives information in pictures and sound about a subject area. The user can use a touch screen to choose among different subjects and problems that he wants to solve. When the user has chosen a subject of interest, he will be able to see a short video film that demonstrates the solution to a concrete problem, such as how to get in and out of the bathtub. DAILY will show how the assistive device works and possible uses. It will also give advice on furnishing the home in such a way that makes everyday living easier and safer. Through multimedia productions, one can add an extra dimension and give information in a way that cannot be done by printed media alone. This makes it possible to see the assistive device in action, how it works, and the different situations it can be used in.

PROGRESS—A prototype has been developed, showing which kind of assistive devices exist and how to use them in the home. Also a small pamphlet has been produced introducing our work.

[131] NEW EXPERIENCES FOR YOUNG CHILDREN WITH PHYSICAL DISABILITIES: DEVELOPING NEW PRODUCTS TO ACCESS EXISTING RECREATION TECHNOLOGIES

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Sponsor: *Lever Foundation*

PURPOSE—Young children with disabilities have the same needs, desires, and rights to take part in the same recreational activities as their nonimpaired peers. However, since many activities require a participant to have good postural control, options are often limited for children who rely on custom seating devices for support. If a means for using custom seats during these activities could be developed, new recreational opportunities could open up for many young children with moderate to severe disabilities.

The goal of this project is to develop a standardized adapter/receiver system for customs seats to allow a child to take part in various recreational activities. This system would readily allow parents to take custom seats from wheelchairs to use as positioning devices on many commercial products such as swings, wagons, and toboggans. Issues such as safety, durability, projected cost, and usability of the system will be considered with consumers and others as it is developed.

METHODOLOGY—Our focus has been to develop an adapter/receiver system to connect custom seats to readily available commercial products. This will provide a low cost alternative to purchasing or borrowing special recreational equipment. We plan to partner with parents and recreational professionals from Bloorview MacMillan and Variety Village to be sure the proposed system is both practical and easy to use.

PROGRESS—Numerous concepts have been developed and informal technical reviews have been conducted. We are presently building working prototypes for evaluation by consumers and recreational professionals using focus group methods. Plans for modifying the prototypes will be created based on the outcome of these sessions.

[132] ASSESSING INDIVIDUALS' PREDISPOSITIONS TO THE USE, AVOIDANCE, OR ABANDONMENT OF ASSISTIVE TECHNOLOGIES

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Sponsor: *National Science Foundation, Ethics and Values in Science and Technology, and Program for Persons with Disabilities, Arlington VA 22230*

PURPOSE—Earlier research classified predispositions to AT use as depending upon characteristics within four major areas: a) the features and functions of a particular technology, b) the preferences and needs of the user, c) the nature of the need for the technology (i.e. disability type and severity), and d) both resources and disincentives in the person's physical and psychosocial environments. The Assistive Technology Device Predisposition Assessment (ATDPA) has subscales to separately assess characteristics of the device, the individual's preferences, the person's view of limitations, and the environments in which the person will use the AT. It is a consumer self-report checklist with 63 items of varied format, including 5-point Likert scales, developed to identify potential sources of person and technology mismatches for early targeted intervention. Side One of the consumer form consists of 53 questions given per consumer on preferences, psychosocial resources, and inquires into an individual's subjective satisfaction with current functioning in many areas and where he or she wants the most improvement to occur. Side Two contains 10 questions for consumers to complete about the technology: their views of and expectations for that particular AT. Companion professional forms are similarly constructed and allow the assessment of shared perspectives between consumer and professional.

The ATDPA is one set of assessment instruments in the Matching Person and Technology (MPT) Model and process. Other instruments are the Worksheet for the MPT Model, Survey of Technology Use (SOTU) and the Educational Technology Predisposition Assessment (ETPA).

METHODOLOGY—To determine the usefulness of the ATDPA in determining reasons for device nonuse or abandonment, 47 persons with mixed diagnoses discharged from an acute inpatient rehabilitation unit completed the instrument at the time of discharge and at 3-mo postdischarge.

To test the value of the MPT process in helping consumers identify the most appropriate technology for their use (and to become more self-determining and independent in the acquisition and use of technology), peer mentors were trained in the MPT process at the Rochester Center for Independent Living. To date, over 25 consumers have been paired with a trained peer mentor.

RESULTS—Among all participants, 128 devices were prescribed; of these, 86 were still used at 3-mo follow-up. For those abandoned, the most frequent reason given was the device was no longer needed, although functional improvement (as measured by the FIM) corresponded with device nonuse for just half the devices. The results from the ATDPA indicated that consumers have positive expectations of devices and, if actual performance falls short of expectations, the response may be to discard use of the device. When consumers seem to over-expect gain from AT use, an appropriate early intervention may be longer trial periods with devices in a variety of situations.

As a means of testing the usefulness of the MPT process in developing a more realistic awareness of AT (both in terms of positive aspects and limitations of technologies), a consumer education program conducted by trained peer mentors has consistently resulted in good person and technology matches, and the MPT mentoring process has been shown to be a cost-effective means of service delivery that has brought more self-aware and knowledgeable consumers into partnership with providers. This has maximized professional time and expertise while yielding an effective, technology-based, higher quality of life for the consumer.

IMPLICATIONS—The results of research and training efforts to date consistently confirm the importance of consumer perceptions and psychosocial factors on decisions to use (or not use) a technology. Early involvement of consumers in technology selection and evaluation determines desirable device characteristics/usability to ensure that a device is a realistic and appealing match for that particular user.

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[133] AN ADAPTIVE TOILETING SYSTEM FOR YOUNG CHILDREN

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Sponsor: *Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health*

PURPOSE—Toileting is an area of concern for many parents of children with physical disabilities. Unless appropriate postural support is provided on a secure base, this event can be frightening for a child and disconcerting for the parent. Our review of commercially available options suggests that many devices are available, but inadequate, because they lack appropriate postural support. A few products have features that can be adapted to seat the child but are beyond the financial means of many families and do not effectively position the child for this activity. Research was conducted to develop a toileting system that would position children better and address issues raised by parents and clinicians.

METHODOLOGY—A take-home prototype was built and used by children in eight families for 1 week each. At the end of the trial period, parents and children were interviewed to understand their views about the performance of the toileting prototype. Families who took the device home were generally very positive about its effectiveness and suggested the incorporation of some minor design improvements to improve its consumer appeal. Suggested changes included increasing hip width, reducing the weight, and modifying the shape of the foot support.

PROGRESS—A final wooden prototype was built and ''dry tested'' with children to verify the size and geometry of the commercial version of the toilet seat. During this phase, locating pads in two sizes were designed to position the hips of smaller children more effectively. A simple, inexpensive form for the footrest was developed to offer two heights for children. We worked with local contractors to translate our design into an aluminum rotational mould. The mould will be used to create hollow plastic parts for the commercial unit.

FUTURE PLANS—We hope to finalize the manufacturing details and consumer instructions and release the product to market fall 1997.

[134] VIDEO, DESIGN, AND REHABILITATION ENGINEERING

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Sponsor: *Royal Brisbane Hospital, Brisbane, Australia 4029*

PURPOSE—We seek to understand the purposeful use of various artefacts (including seat components and wheelchairs) in relation to utterances by participants in a client assessment and design/manufacturing process providing customized seating for people with severe physical disabilities. The value of this work is in developing techniques that will enable an assessment and design group remote from the client to manufacture customized devices via video conferencing technology. The development of these techniques will expand the availability of specialized assistive technology services to people with disabilities living in remote locations and reduce the cost, inconvenience, and trauma of people with disabilities having to travel to large cities to receive specialized services.

METHODOLOGY—The activities of a rehabilitation engineering team have been observed over a 3-yr period. Videotapes of team practice are being analyzed to explore the relationship of, and the use of, action in association with talk to communicate design ideas.

PROGRESS—We have found that purposeful actions, such as using hands to locate design intent, creating mock-ups of ideas using simple components, and shaping hands convey more design information for manufacture than oral utterances of the team members. There appears to be reliance on visual representation as the main communication medium. Work is continuing on techniques to capture the visual data and make it available quickly to guide manufacture.

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[135] AN EVALUATION OF THE ACCESS GLIDE SYSTEM FOR MOUNTING AUGMENTATIVE COMMUNICATION DEVICES: A PILOT STUDY

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Sponsor: *Thames Valley Children's Centre, London, ON, Canada, N6B 5Y6*

PURPOSE—There are times, such as when driving a wheelchair or toileting, when users of augmentative communication devices do not need their devices to be positioned in front of them. Accidental damage to equipment can result when devices must be removed from wheelchairs, causing inconvenience to the user. The Access Glide System (AGS) has been designed to address the issue of equipment placement. Mounting hardware that incorporates a linear motion system allows for storage of the device behind the wheelchair canes without physically removing the equipment from the chair. The system is designed to be operated manually by caregivers. This pilot study evaluated the effectiveness of the AGS from the perspective of both clients and caregivers. Specifically, nine consumer-based criteria for the evaluation of assistive devices were examined: effectiveness, operability, dependability, personal acceptability, the extent to which the consumer can easily learn to use the device, physical security, physical comfort, portability, and securability.

METHODOLOGY—Four clients needing augmentative communication devices and 13 individuals who interact with the clients on a regular basis (e.g., parents, therapists, educational assistants, and friends) participated in the study. Clients represented a range of ages and living situations. They used the AGS for a period of at least 6 wks before giving feedback to the researchers in home interviews. Clients distributed questionnaires to other individuals they felt would have enough interaction with the AGS to provide useful feedback.

RESULTS—The AGS was found to be an effective and useful mounting system. All clients reported using the system several times a day. The system allowed clients and caregivers to store their augmentative communication devices safely and efficiently behind their wheelchairs. Moreover, the system increased clients' access to their devices. Caregivers found it took a matter of seconds to slide the device to a position in front of clients for use. The system was easier for caregivers to operate, compared to previous equipment, because they did not have to detach and reattach the device to the chair for each change in functional activity. As a result, clients reported that their independence had increased.

FUTURE PLANS—Feedback from the study participants will be included in further design refinements of the system. We next will demonstrate the AGS at augmentative and alternative communication centers across Ontario. A questionnaire is currently being designed to gather feedback from therapists and technicians on other evaluation criteria such as: ease of assembly, compatibility with other devices, durability, and ease of maintenance. Further steps include the development of a broader marketing plan.

[136] SPECIAL PROJECTS AND DEMONSTRATION: APPLICATIONS OF TECHNOLOGY TO ENHANCE QUALITY OF LIFE—A COMMUNITY MODEL

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PURPOSE—The project focuses on demonstrating that the education and rehabilitation planning processes for individuals with significant disabilities can be enhanced by appropriate applications of technology. The project intends to demonstrate that persons with severe disabilities using customized adaptations (assistive devices) can participate more meaningfully in integrated work, school, and other community settings; to involve educators, rehabilitation counselors, case managers, teachers, parents, employers, future engineers, and community members with technical expertise in the development of adaptations; and to develop a replicable approach for enhancing the applications of assistive technology through direct service, information collection and dissemination, and referrals.

PROGRESS—To identify individuals who could benefit from customized technical adaptations, the project staff worked closely with teachers and resource specialists of the San Diego Unified School District as well as staff from local supported employment and supported living agencies. The project targeted transition-aged students (18–22 years) and young adults who, with suitable individualized assistive technology, could become more active participants in school, work, and community settings. Resources were utilized to build up the technical capabilities of local schools and service agencies, expanding the network of rehabilitation and assistive technology professionals, and reducing possible duplication. The project successfully exceeded its goals in terms of number of persons helped and technical adaptations completed.

One key component of the project was the use of multidisciplinary tech teams, individually focused on the specific needs of the consumer. These teams included friends, family members, interested volunteers, and employers, in addition to the special educators, engineering students, OTs/PTs, speech therapists, and community-based rehabilitation professionals who were enrolled in a special seminar jointly taught by the Departments of Special Education and Electrical Engineering. In addition to providing valuable hands-on experience of designing and fabricating a customized assistive device, the seminar facilitated exchanges of ideas and diverse viewpoints. The Interwork Technology Mini-center coordinated various demonstration, training, research, and dissemination activities associated with the project while also serving as a repository of numerous reference materials available for use by the community and the teams. Information about on-going projects and completed projects have been disseminated in print and via the Internet at http:// www.interwork.sdsu.edu/projects/.

RESULTS—Major accomplishments after 48 months include: 1) better collaboration with the school district, supported employment, and supported living agencies through better utilization of each others' assistive technology resources and expertise; 2) expanded key intra-state and inter-state linkages; 3) design, fabrication, and delivery of over 40 customized technical adaptations; 4) documentation of individualized adaptations using photographs, videotape, technical drawings, and case study descriptions; 5) presentations at the local, state, and national levels; 6) evaluation of the completed projects; and 7) establishment and maintenance of a local web site that describes project activities and accomplishments.

Recently completed customized adaptations include: a wheelchair-mounted laptray with a hinged plexiglass cover that prevented the unwanted removal or destruction of instructional and communication materials placed there. Modification of a bicycle to permit independent mobility by an undersized 4-year-old girl; to accommodate her physical limitations, the bicycle's seat was lowered, its handlebars were bent backwards, the pedal cranks were shortened, and the gear ratio was changed. A substitute custom-made universal remote control with large buttons and labels that enabled an 11-year-old sixth grader to control the TV, VCR, and radio in his classroom. A front-mountable shopping/utility bag for a powered wheelchair, to enable an elderly woman to carry groceries: the bag was made of industrial grade mesh cloth, the support frame and wheelchair brackets of aluminum. A customized tiltable laptray to hold papers and other school work for a 10-year-old boy with congenital myotubular myopathy; the laptray was fitted to a reclining, powered wheelchair that had bilateral joystick controllers and ventilation equipment.

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[137] TRANS-TRAIN: TRANSDISCIPLINARY TRAINING OF REHABILITATION PERSONNEL IN ASSISTIVE TECHNOLOGY

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PURPOSE—Project TRANS-TRAIN seeks to provide preservice and inservice training to rehabilitation personnel in Assistive Technology. It is a university-based program that combines academic classroom instruction with experiential field activities. Although discipline specific training will occur, TRANS-TRAIN fundamentally is a transdisciplinary project that establishes a series of courses, guided design projects, and internships that focus on the development and use of assistive technology. Six- to nine-unit curricula sequences are being offered and co-listed in the Departments of Special Education and Rehabilitation graduate degree and certificate programs and in the Electrical and Computer Engineering undergraduate and graduate degree programs. To complement an existing certificate program in Supported Employment and Transition, a specialization area in Rehabilitation Technology is being developed.

METHODOLOGY—Because students enter from various educational and vocational backgrounds, such as engineering, special education, rehabilitation counseling, communicative disorders, and social work, the certificate program will be customized to fit their backgrounds, skills, interests, and intended application areas. In addition to the six- to nine-unit curricula, students seeking a ''Certificate in Assistive Technology'' complete six units of formalized, discipline-specific coursework from their home departments and three to six units of transdisciplinary seminars covering a broad range of rehabilitation technology competencies and knowledge. For hands-on experience, students participate in a number of internships, off-campus and on-campus, under the supervision of professors and practicing professionals in rehabilitation engineering, special education and rehabilitation, and communicative disorders, by working at local agencies.

PROGRESS—During Fall 1996 and Spring 1997, 20 undergraduate and 1 graduate engineering students, 14 graduate students in special education, 3 graduate students in rehabilitation counseling, 1 physical therapist, 2 assistive technology suppliers, and 2 technically proficient community members participated in the transdisciplinary seminar.

Tech teams were formed around individuals with disabilities who needed some sort of adaptations. Some of the adaptations designed, fabricated, field tested, and delivered inclue:

1. A powered jump rope turner was adapted for a fifth grader with cerebral palsy (CP). The adaptation included a battery power drill mounted on the arm of her wheelchair, a joystick controller, and a large wheel that spun the jump rope.
2. Teacher attention-getter for a 7-year old boy with CP. A snake light was attached to the power chair and operated by the boy using an on/off switch mounted to a movable bar.
3. Off-Road walker for an 11-year old with CP. The device can be fitted with either two or four oversized plastic wheels and was carried on his wheelchair by a pair of Quickie armrests, turned backwards.
4. Revamped walker with carrier to enable a high school student with CP to transport his lunch and to work in an office. A modified bike bag was attached to a swing-away bar, clamped across the front-opening walker.
5. A more functional lap tray to enable a 6th grader to manipulate the drive wheel of his manual wheelchair while also use his laptray as a communication board and desktop.

RECENT PUBLICATIONS FROM THIS RESEARCH

From snake lights to power drills: using adaptive devices to support students with disabilities in schools. Sax C. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press; 1997.

[138] A MUSICAL INSTRUMENT DIGITAL INTERFACE FOR CHILDREN WITH PHYSICAL DISABILITES

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Sponsor: *None listed*

PURPOSE—Recreation is part of every child's growth and development, but children with severe physical disabilities are limited in the activities they can pursue independently and with their peers. The proposed project aims to broaden the scope of possibilities for recreation and social interaction for such children through the creation of a single switch interface for a Musical Instrument Digital Interface (MIDI) keyboard, and addressing how to best integrate music into education, therapy, and play. MIDI is a universal standard that allows musical keyboards and instruments to communicate electronically.

PROGRESS—A prototype device that allows children to play music independently with a single switch has been developed. The device will consist of an LCD display, adapted switch inputs, a MIDI connection for electronic keyboards, and a removable cartridge containing a microprocessor with software to play music. Initially, two demonstartion cartridges have been produced. One cartridge will allow users to play individual notes, chords, and arpeggiated chords from one, two, or three switches, with a fourth switch for the control of tempo and the fundamental note being played. This cartridge will allow individuals or groups to play harmony and accompany virtually any song or melody. Virtually any instrument, or even choral music can be played. The second cartridge is a melody cartridge to allow children using single switches to play from a choice of approximately 10 melodies. The tempo and timing of the music will be controllable by the user.

FUTURE PLANS—Music cartridges containing approximately 20 songs each will be created for a variety ages and musical tastes. Age- and ability-appropriate activities and programs will be developed for using the new technology, and musical activities, rhythm games, and songs for individuals, pairs, and larger groups will be developed and evaluated. Emphasis will be on identifying and developing music that is varied and interesting, while requiring only a limited number of chords and notes to play. Activities that emphasize rhythm, playing sounds on cue and alternating play between individuals will be developed and piloted as part of this project. A manual for Occupational, Physical and Music therapists outlining the activities developed in this project will be produced. The development of a methodology for measuring the psychosocial benefits of the musical activities made possible by this project is planned for the coming year.

B. Robotics

[139] DEVELOPMENT OF AN ASSISTIVE ROBOT FOR EFFECTIVE HEALTH CARE DELIVERY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B899-2DA)*

PURPOSE—Over the past 7 years, veterans with high level quadriplegia have been testing the ability of the DeVAR robotic workstation to replace an attendant for independent execution of vocational tasks. These tests have proven feasibility, and along with the recent VA Technology Transfer Section (TTS) evaluation, have clarified the next necessary phase of development that will advance the workstation to successful commercialization. The primary goals for this phase are more functionality per dollar, easier operator control, and higher system reliability.

The research plan involves 1 year of intensive design and low-level development, including evaluation methods and materials, 1 year of iterative development and evaluation cycles of subsystems, and a third year of in-clinic full system evaluation at this facility's Spinal Cord Injury Center.

METHODOLOGY—Increased functionality will be achieved by refining the current DeVAR interface so that users will be able to design their own robot tasks without having to become programmers of the robot to do so. Adding force and touch sensors that detect surfaces and objects will then allow the robot to make adjustments when needed, and verify that tasks are done correctly and safely. The combination of the new interface and the sensors is the key to a successful implementation, since neither advance alone will meet the challenge of providing effective user control of robot programming.

The reliability of the robot will be increased by a commercial control system that integrates motion, sensing, and communication functions. The controller will be networked to the interface computer, with a link to the Internet. This modular approach will enhance reliability, and will provide a rich, multimedia communication path for troubleshooting, training, and information exchange between the user, the robot manufacturer, therapists, and other users. The TTS evaluation demonstrated the tremendous importance of communication to system maintenance and downtime reduction. We will customize network-based software for remote diagnostics and troubleshooting that will allow for fast response to problems that arise.

PROGRESS—The start-up phase is complete. We have identified, specified, and procured the necessary hardware and software for adaptive access, robot controller, user interface, networking, and sensor subsystems. We have specified critical communication and modeling protocols. Interface and controller programming is ongoing. Evaluation methods and materials from previous DeVAR evaluations are being used to develop augmented data instruments. Collaboration with Spinal Cord Injury Center clinical staff is ongoing to develop task lists, user profiles, and staff clinical needs.

A suite of adaptive access equipment for a Windows environment has been chosen to allow operators to use head motion, speech, and residual arm motion to operate a keyboard, pointing device, and other communication equipment. The interface design is based on WWW standards for modeling and communication. VRML and JAVA-based standards have been chosen for their platform-independence and for the support they will continue to receive in the future by the computer industry. General concepts for the design of the interface have been prototyped. The controller software is based on a real-time operating system and code developed for full dynamic control of a PUMA robot.

[140] CUSTOMIZATION OF A SPACEBALL INTERFACE FOR THE MANUS ROBOT ARM

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Sponsor: *None listed*

PURPOSE—Rehabilitation robots, such as the Manus, can enable children to independently explore and manipulate their environments, provided that the robot is simple and intuitive to control. Traditional controllers like joysticks or keyboards are too limited, or too nonintuitive to allow for obvious control of a robot arm. They require the user to switch among many different modes. In addition, these controllers are difficult to use for people with tremors or spasticity. The Spaceball is a ball-shaped computer input device that remains stationary while a user exerts light pressure to push (left/right, forward/backward), pull (up/down) and twist and turn it in different directions. Because it allows for motion in 6 independent directions, there is no need for mode switching when using it to control the robot arm. The Spaceball is also programmable, which enables it to be customized according to different user needs.

The primary objective of this research is to enable children and young adults with variable strength and control of their hands and limbs to use the Spaceball as an interface to the Manus robot arm so that they may independently explore and manipulate their environment.

METHODOLOGY—We must first determine which groups of physically challenged children can derive the most benefit from the Spaceball-Manus manipulator combination, along with the prerequisite conditions that these groups would require for successful use of it. Then we must design a system that allows these parameters to be easily configured and adjusted such that children and young adults with different characteristics may use the conbination with equal effectiveness. Finally, we shall evaluate the designed system by comparing its performance with that of the standard Manus interfaces of keyboard and joystick.

PROGRESS—The hardware interface has been reconfigured and is currently being tested. Participants are currently being recruited for the clinical trials.

FUTURE PLANS—Two studies will be conducted: In the first, eight expert users will use the Manus with three different interfaces (keyboard, joystick, and Spaceball) to perform three tasks. Time to completion and number of successfully completed steps in each task will be used as measures to determine whether there is improved performance with the Spaceball. In the second study, participants between the ages of 12 and 18 with cerebral palsy, spina bifida, arthritis, and muscular dystrophy will perform the same three tasks with the Spaceball with and without customizations and the same performance measures will be recorded. Data collected will be analyzed and a final report of the results prepared.

[141] ALTERNATIVE CONTROLLERS FOR THE MYOELECTRIC QUADRAPLEGIC ASSISTIVE DEVICE (MYQUAD)

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Sponsor: *None listed*

PURPOSE—This project proposes a four-position analog joystick as an alternative controller for the Myoelectric Quadraplegic Assistive Device (MyQuad).

METHODOLOGY—The myoelectric quadraplegic assistive device is a wheelchair-mounted robot designed for the high-level quadriplegic group. Five degrees of freedom (DOF) are offered: axial rotation, height, telescopic, terminal device rotation, and terminal device prehension. The existing myolectrical controllers allow movement in either positive or negative direction in a single axis, in conjunction with a head switch, and require five modes each controlling one degree of freedom. (5 modes×1 DOF=5 DOF).

An analog four-position joystick allows intuitive control in the x-y axis but not for the remaining three functions of the MyQuad, thus a switch between modes during control is needed. Indeed one of its functions has to occur in more than one mode in order to use the six possible DOF offered by an x-y axis joystick (3 modes×2 DOF=6 DOF).

Compared to the five modes used by the myoelectrical controller, a joystick offers a more effective and intuitive means for controlling the MyQuad. People with high-level quadriplegic injuries are unable to use this technology. However, for people with muscular dystrophy, the joystick may be a suitable alternative controller.

PROGRESS—In order to minimize the number of times that the user changes mode by pressing a switch, eight experiments were done to find out what functions should be paired in the three modes. Other experiments show that with the proper strategy, reaching and grasping an object can be achieved in less time. Also it was found that the functionality of the Myquad depends on the size, weight, and the shape of the object. Also, the time taken to get an object is reduced as the user is familiarized with the MyQuad. It is likely a learning process.

Currently, an interface is being developed between the MyQuad and a four-position joystick.

FUTURE PLANS—Future work may include controlling the arm through a computer program.

C. Communication Methods and Systems

[142] DEVELOPMENT OF AN ASSISTIVE MEMORY DEVICE FOR PATIENTS WITH SEVERE AMNESIA: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #F471-5PA)*

PURPOSE—The specific purpose of this investigation was to evaluate whether an assistive device shown to be effective with persons with pure amnesic disorders (Korsakoff's syndrome) can be productively applied to brain-damaged persons with multiple deficits including, but not restricted to, memory. The study planned was concerned with densely amnesic individuals, and with the evaluation of a small, portable device that subjects can use to access ADL relevant information. Training to use the device involved a conditioning procedure shown to be effective in previous research. The major goal of the study was that of determining whether subjects could be successfully trained to use the device, and whether such training substantially improved memory function in everyday life.

METHODOLOGY—Subjects were recruited on the basis of presence of severe memory disorder associated with Alzheimer's disease, or other neurological illness associated with severe dementia and amnesia. A neuropsychological assessment was used to determine eligibility for the study. Subjects meeting inclusion and exclusion criteria were to be introduced to the training device and engage in the conditioning program that involved teaching subjects to use the device with increasing independence in order to access information. The goal of the program was to teach the subject to independently use the device upon a verbal request for information that the device contained. Learning curve data would be accumulated and various measures, administered before and after training, were to be used to assess outcome.

PROGRESS—Substantial effort has been made to recruit subjects for this study. Of 13 persons approached who met the criteria of severe amnesia and other cognitive deficits, mainly patients with Alzheimer's disease, all either did not meet psychometric inclusion criteria, could not cooperate for psychometric testing, or could not understand the requirements of the training. We were unable to enter any subjects with diagnosed Alzheimer's disease who could cooperate for the program. Our conclusion from this pilot work is that training to use an assistive memory device, while effective with patients with severe but pure amnesic disorders, is unlikely to be effective for patients with progressive dementia.

FUTURE PLANS—We remain committed to finding effective methods for improving functional capacity and quality of life for brain-damaged persons. However, we appear to have convincing evidence that a method shown to be remarkably effective for patients with a neurobehavioral disorder involving a single domain, in this case memory, was not found to be effective in patients with more generalized cognitive dysfunction. Perhaps usage of "smart" technologies in these patients' environments would be more productive.

RECENT PUBLICATIONS FROM THIS RESEARCH

An assisitive device for severely amnesic patients. Goldstein G, Beers SR, Shemansky WJ, Longmore S. J Rehabil Res Dev. In press.

[143] COMPUTER ACCESS SELECTOR AND VOCASELECT

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Sponsor: *The Crippled Children's Association of South Australia, Inc., Regency Park, SA 5942, Australia*

PURPOSE—Computer Access Selector and VOCAselect are computer programs that aim to assist in the selection of alternative computer access and voice output communication devices respectively, a process that, for an individual with a disability involves a compromise of many different parameters. Professional assessment is generally required to determine his or her the needs and abilities, and selection of specific products is not necessarily straightforward, due to the number available. Computer Access Selector and VOCAselect narrow down the large number of products, on the basis of feature selections made by the user.

METHODOLOGY—The user specifies the requirements of the computer access system or voice output device he or she is looking for by selecting from a series of parameters, and the programs use expert knowledge to suggest potentially suitable products. The suggestions are dynamically adjusted as user selections are changed. This provides a means for the user to explore different possibilities and trade-offs. A click of the mouse reveals details about a product and shows a picture of it on-screen. Manufacturer and Australian supplier contact information is provided in the product details. The software can be instructed to generate a report of the user's findings for printing or inclusion in a word processing document.

PROGRESS—Computer Access Selector version 1.0, a Windows-compatible program, was released in 1995 and offered free for evaluation purposes; it has now been distributed to a large number of interested individuals, professionals, and organizations. VOCAselect version 1.0, a Macintosh-compatible program was also released in 1995, and has now been distributed widely. Following suggestions from the users of the Macintosh version of VOCAselect v1.0, VOCAselect version 1.9 (Windows-compatible) was released in 1996. All programs have undergone alpha and beta testing prior to release, and are available for A$50 each, +A$10 postage and handling.

RESULTS—Feedback and responses have been sought from users, primarily via a survey questionnaire sent with the software. The survey results have been used to assist in the development of the next versions of the programs.

FUTURE PLANS—Refinements based on user response will continue to be made to ensure that the programs continue to be relevant and valuable tools for all who need to choose alternative access and voice output technology. The product information contained in both software packages is expected to be updated annually. Version 2.0 of both packages with updated product information will be available by late 1997.

RECENT PUBLICATIONS FROM THIS RESEARCH

Computer access selector: a tool to assist in the selection of computer access devices. Stapleton D, Garrett R, Stewart H, Seeger B. Proceedings of the 2nd Australian Conference on Technology for People with Disabilities; 1995, Adelaide, Australia. Regency Park, SA: The Regency Park Centre; 1995. p. 128–30.

VOCAselect version 1.0: an AAC device selection tool. Stapleton D, Garrett R. Proceedings of the 2nd Australian Conference on Technology for People with Disabilities; 1995, Adelaide, Australia. Regency Park, SA: The Regency Park Centre; 1995. p. 114–6.

[144] CELLINK, CELLULAR TELEPHONE INTERFACE

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Sponsor: *Industry Canada, Ottawa, ON Canada K2H 8S2; Bloorview Foundation, Mitsubishi Canada, OKI Telecom, Nokia Products Limited, Bell Mobility*

PURPOSE—Access to a cellular telephone allows for immediate communication whenever and wherever a person wishes to place a call. Many commercial telephone devices address the needs of personal communication for persons with disabilities only when they are used in their home environment. This important communication link is lost outside the home. The community is increasingly becoming more accessible to people with severe disabilities, resulting in additional vocational and recreational time spent outside the home. Personal safety and security can be enhanced by cellular telephone technologies. Persons with more severe disabilities could have their personal communication needs accommodated through wheelchair-mounted cellular telephones requiring minimal physical input to operate.

PROGRESS—Manufacturing prototypes of the CELLINK, cellular telephone interface, have been constructed. A consumer focus group was established to identify important adapted telephone features and to perform its field evaluation. All consumers used powered wheelchairs and had normal visual acuity and hearing. Three controlled their wheelchairs using proportional joysticks, one with a Peach Tree head control, and one a SIP&PUFF control. Two used portable ventilators and one used a phrenic nerve pacer.

A criterion for inclusion in the field evaluations was that there be no observable electromagnetic compatibility issues between the cellular telephone and any of their assistive technology (AT). An empirical test was performed with each subject's AT to verify compatibility. None observed any unusual dysfunction of their AT while using the device. It was strongly advised that they should not operate the phone while driving their wheelchair.

RESULTS—All had used their phones for between 2 and 5 mo before the follow-up evaluation was conducted. Typically, the CELLINK was used for personal calls to stay in touch with friends and family. The second most frequent use was for somewhat essential community calls to reschedule transportation bookings. One consumer needed to dial 911 for a personal medical emergency.

All felt that the phone increased their independence, ability to get help in a timely manner, personal safety, and their ability to acquire transportation. Some felt that having the CELLINK gave them the security to spontaneously go places with their wheelchair where they normally would only have gone with organized transportation. They were less concerned with becoming stranded in the community, which promoted more outings.

The features that they found most effective were the dialing directory, last number redial, and the priority dial. When asked what other features they would like, they responded: connect to home computer, control land line telephone, and control home entertainment equipment. Three felt that it was a convenience to have cellular telephone access, while two felt that it was a necessity. All felt that they would use a cellular telephone in conjunction with their land line home dialer.

FUTURE PLANS—Further investigation is required with a larger consumer population to determine the significance of personal cellular communications to greater community independence and safety. A collaborative quality-of-life investigation is planned to include 40 consumers with severe disabilities who use powered wheelchairs for mobility and who are unable to use commercial cellular telephones.

[145] FRENCH WIVIK

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PURPOSE—WiViK and KeyREP are compatible with all international (foreign language) keyboards supported by Windows. However, the user interface and on-line and printed documentation are in English only. As a start to providing full support in other languages, a French version of the software and documentation has been produced. The immediate markets are persons in Quebec and other French-speaking Canadians, as well as persons in Europe. To ensure that the French products are of high quality, a formal evaluation was held with participants in Quebec and Europe.

PROGRESS—The interfaces for WiViK and KeyREP have been completely translated into French. New standard and macro keyboards were designed to incorporate accented characters and different country layouts. During this process we learned a great deal about the real complexities of providing a simple-to-use keyboard when accented characters are involved. Sample French word prediction dictionaries and abbreviation-expansion sets were also created.

Some improvements in the software were made to facilitate translation. This should make translation into other languages easier. The layout structure for the manual was standardized so that the document design task was considerably simplified.

FUTURE PLANS—Our translated WiViK and KeyREP products were released in 1997. Future work may include translation into French of other products such as WiVox and upcoming product upgrades.

[146] EVALUATION OF OVERDRIVE SCANNING

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PURPOSE—Overdrive scanning was evaluated as an enhancement to text scanning strategies to potentially reduce scanning time. Overdrive scanning allows subjects to control a faster scanning rate through the use of a second switch. It attempts to reduce the time that the user must wait as scanning proceeds across many items. This time may be viewed as wasted.

METHODOLOGY—Two methods for overdrive have been designed and programmed into WiViK. One method takes advantage of a second switch with a timed hold and release action. As long as this second switch is held, the scan interval is shortened by some factor, thus increasing scan rate. When the switch is released, the scan interval returns to its original value. Recognizing that some users may not be able to perform such an action, another method has been designed to take advantage of a second switch with a discrete activation to toggle the original scan rate to a faster rate. A second activation toggles the rate back to its original value.

A between-subjects design was employed utilizing two groups of 10 nondisabled subjects each in this experiment. Each group used one of the two overdrive methods in four sets of trials. Each of the four sets of trials performed by each group included 30 test trials in which each of the 15 target items were tested twice.

PROGRESS—With both methods, there was a clear tradeoff function associated with using overdrive. There were three target distance zones in which subjects demonstrated overdrive usage: a 'no' zone in which the user would definitely not choose overdrive; a 'maybe' zone in which the user might use overdrive; and a 'yes' zone in which overdrive would always be used. The maybe zone had questionable benefit in terms of time savings and greater errors. The yes zone had significant time savings in the order of 40–60 percent which can translate into several seconds. With the first method, this zone began after the fifth or sixth item (depending on overdrive speed). With the second method, this zone began later after the eighth or ninth item, which can be attributed to the state of tension over toggling the overdrive on and off. In both cases overdrive was initiated almost immediately and maintained as long as possible before releasing to return to the regular scan interval to select the target.

Although an overdrive function has the potential for significant time savings, it is only useful when the dimension of the scanned items lies in the yes zone and if the user has the physical ability to use it. Generally, overdrive is not useful while moving across text objects. Only when scanning across many words in a line is the advantage of overdrive obvious, although words could be scanned in groups of several words and overdrive would not be used at all. However there are circumstances in which it is faster to scan with overdrive across many items than it is to scan in groups. Overdrive has potential benefit when targeting items near the end of a larger group, and little or no benefit when targeting items at the start of a group.

[147] EVALUATION OF TEXT SELECTION STRATEGIES

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PURPOSE—Three new strategies for positioning the insertion point by scanning the text were compared with each other, and with a standard keystrokes strategy. First, a predictive analysis was used to estimate error-free performances. Second, an experiment was conducted with subjects to gain knowledge of user strategies, short-term learning, errors, and perceptions that cannot be predicted.

METHODOLOGY—The scanning-text-keys strategy uses repeating text keys to engage the cursor in scanning across text objects. Sequential scanning text keys links text keys to permit the user to scan to a target point in a single operation through a sequence from large to small groups (paragraphs, lines, words, characters) allowing him/her to focus on the target location and to activate the select switch whenever it is highlighted.

A between-subjects design was employed, utilizing four groups of five nonimpaired control subjects. Each group used one strategy in five sets of trials. Each set included 25 trials of selecting blocks of text.

PROGRESS—As expected, the standard keystrokes strategy was the slowest, used the most on-screen keys, required the greatest number of select switch activations, and resulted in constant attention switching between the text area and the on-screen keyboard.

The scanning-text-keys strategy significantly reduced the number of key selections and switch activations. It was easy to use, and subjects had control over all cursor movements. Time was reduced by approximately one-fifth. A particular usability problem was confusion between repeating and nonrepeating keys available on the on-screen keyboard.

The sequential-scanning-text-keys strategy substantially reduced user demands. A drawback was that the users did not have control over the direction of movement, resulting in some inefficient movements and a feeling of some loss of control. Planning and attention switching between the text area and on-screen keyboard were minimized. Time savings were, however, equivalent to the repeating keystrokes strategy. This strategy had some specific difficulties including: extra vigilance to constantly compare the location of the text cursor with the target location; confusion regarding the current scanning level; and error correction.

The text-scanning strategy had similar efficiencies as the previous strategy with fewer errors of over and undershooting because of the easier selection rule and the visual feedback of the highlighting block that indicated movement size. However, time performance was poorer because it was more difficult to stop scanning after overshooting the target and it took longer to make corrections. Although consistent with scanning the on-screen keyboard, subjects felt loss of control over the cursor as they retained a text cursor mental model.

It is not suggested that any one strategy is best. All strategies work within the task transparency concept. The observed improvements can have a significant impact in minimizing the physical and cognitive demands of switch-based scanning.

[148] TOWARD TASK TRANSPARENCY IN ALTERNATIVE COMPUTER ACCESS: SELECTION OF TEXT THROUGH SWITCH-BASED SCANNING

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Sponsor: *National Health Research and Development Programme, Health and Welfare Canada; Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health; IBM Canada Ltd.*

PURPOSE—We refined the interpretation of transparent computer access for people with physical disabilities, called task transparency. The goal was to derive new knowledge and understanding of the interactions that arise through a number of strategies that apply switch-based scanning to text selection in a task-transparent fashion. The results should provide valuable directions toward the design of access systems that enable users of indirect scanning access methods to not just achieve equal access, but to achieve equal productivity.

METHODOLOGY—Our research demonstrated that, in the case of selecting text, directness to the task can be achieved with minimal effort by applying scanning within the text area itself. The concepts are readily extended across other GUI objects, including menus, buttons, and window controls. These objects can be incorporated within the access system so that they are directly engaged in the scanning.

PROGRESS—It is proposed that the concept of transparency be revised so that alternate access systems follow a design allowing the user to directly access the underlying tasks and data without requiring the performance of equivalent functions to the standard input devices. This task transparency approach maintains the original concept of transparency, but focuses attention on what the user wants to accomplish by working at the application task level, rather than the operational tasks associated with standard input devices.

Text scanning was implemented using repeating keys injected by an on-screen keyboard so that the user perceived scanning in the text area. Two test applications were developed and used to evaluate a number of proposed text scanning strategies. In addition, predictive performance models were derived to predict performance measures under error-free conditions.

Design guidelines for scanning in a task-transparent fashion have been formulated. Although further work is required, these provide a foundation: sufficient knowledge is provided that a developer of access systems could extend the concepts in new ways with scanning and other access methods, and we have mapped future areas of research that may improve overall productivity and identified areas of concern.

[149] EFFECTIVENESS OF USING VOICE RECOGNITION SYSTEMS

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Sponsor: *Ontario Ministry of Health's Neurodevelopmental Clinical Research Unit*

PURPOSE—The purpose of this pilot study is to evaluate the use of voice recognition to create text and the effects of discrete utterance speech on participants' voices.

METHODOLOGY—Participants are clients between the ages of 19 and 35 who have been prescribed voice recognition systems to use as writing aids. Six have been recruited for this preliminary study and asked to complete various typing tasks and to answer questions regarding the use of their system. Speed and accuracy of text generation, and the voice recognition system's accuracy will be calculated. Tape recordings of each participant's speech will be obtained in order to evaluate voice quality. Responses to interview questions will be analyzed descriptively.

PROGRESS—All six have completed the above protocol. Each has a different diagnosis (e.g., muscular dystrophy, upper motor neuron disease, scleroderma, and thoracic output syndrome). An additional participant will be recruited since one of the above participants had not been using her system and therefore various tasks were difficult for her.

PRELIMINARY RESULTS—Results from four participants have been analyzed:

Speed of Text Generation and Accuracy

Relative speed of text generation for the various tasks generally showed similar patterns for each participant. Dictation of numbers resulted in the slowest rate (a group average of 5.2 wpm), whereas dictation from a copy of the participant's previous work resulted in the fastest rate of text generation (a group average of 19.4 wpm). There was individual variation. For example Participant D's slowest dictation rate was for dictation of her name and address (5 wpm). For Participant A, dictation of a letter was the fastest task (10.8 wpm). Individual recognition accuracy scores ranged from 59 to 100 percent. Average recognition accuracy for the group ranged from 68 percent for copy dictation to 80 percent for copy dictation of previous work. There were individual variations. Participant D was recognized least on the name and address dictation task (53 percent) and Participant A was best recognized on dictation of numbers (100 percent)

Client Satisfaction and Manipulation of Applications

One out of the four participants reported that the voice recognition system allowed her to complete the tasks required to be done. All commented that the advantage of their voice recognition system was that it allowed them to write without using their hands. For some, voice recognition was reported to be faster than other methods of computer access (e.g., on-screen keyboard). Each reported at least one of the following problems with use of voice recognition: fatigue (both physical and mental), poor recognition, slow speed of text generation, limited access to applications other than word processing, and the need to produce consistent speech. Some did not find the system easy to use because of the tedious procedures required to correct voice recognition errors. Other problems were lack of confidentiality and privacy, and interference with recognition from noisy environments.

Voice Problems

Three out of four reported voice-related problems subsequent to using their voice recognition systems. Specific problems reported included hoarseness, vocal fatigue, sore throats, coughing, increase in mucus and decrease in loudness. A referral to an otolaryngologist was recommended for two; this assessment did not reveal any abnormalities for one of them, and the second had not been examined at this writing. The two who followed the vocal hygiene recommendations did not report any of the above problems except vocal fatigue.

[150] COMPUTER SOFTWARE TO ASSESS VISUAL LEARNING PROBLEMS

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PURPOSE—The Componential Assessment of Visual Perception (CAVP) is a Windows product for measuring the visual-perceptual skills of people aged 8 years to adult. It measures visual-perceptual skills in discrimination, memory, selective attention, and search. With young children, the CAVP can be used to help identify children quickly who are at risk for visual and perceptual problems. With adults, the CAVP can be used to help identify treatment options for clinical professionals. In many instances, treatment options include assistive technologies, such as computer programs to improve reading and writing skills, whose effective prescription will improve because of the assessment and diagnosis capabilities of the CAVP.

The CAVP is designed for use by psychologists, therapists, teachers, and educational specialists in clinical and school settings, and on home visits. Research studies are underway to develop normative data. In the meantime, the CAVP can be used as a supplement to other, standardized clinical tests, to provide a more detailed analysis of visual-perceptual skills.

PROGRESS—The CAVP's computerized presentation format automates many of the administration requirements of popular measures like the Test of Visual-Perceptual Skills (TVPS) and the Motor-Free Visual Perception Test (MVPT). This helps to standardize test administration, and frees the professional to be a more effective observer of the client during test performance. Response times and accuracy are measured reliably and precisely. The CAVP records the strategies used by the client to solve visual-perceptual problems, under a variety of environmental conditions. Unique report features allow the professional to identify ways to improve personal strategies or modify the visual environment, as needed, to benefit visual-perceptual performance in the real world. The CAVP can accommodate a variety of pointing devices, including hands-free devices such as a head pointer. This makes it a valuable tool for assessing visual-perceptual abilities without involving motor skills. This is an especially important feature for professionals who assess clients with learning disabilities, motor impairments, or physical disabilities.

FUTURE PLANS—The CAVP is being prepared for commercial release in a research version. This is similar to other cognitive rehabilitation tests for which complete normative data are not yet available, but which can be used immediately for research purposes, and to enhance the interpretation of results obtained from other, standardized assessment tests. Proposed upgrades include: improved reporting capabilities and compatibility with other popular software products; new sets of stimulus materials, such as pictures and photographs of familiar objects; new options for use with pointing devices; normative data from normal and special populations, as they become available; and greater facility for user customization.

[151] WIVIK 2 ON-SCREEN KEYBOARD

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PURPOSE—WiViK 2 enables people with physical disabilities to use Windows applications for school, work, and play. WiViK displays a customizable keyboard on the computer screen. Users type with any pointing device including a mouse, trackball, joystick, pointing pad, touchscreen, pen, or advanced devices, such as headpointers and eye-gaze. Simply clicking or dwelling on the desired key's image activates that key's function. Those with greater physical limitations may use a single switch.

People who benefit include those with cerebral palsy, spinal cord injuries, muscular dystrophy, multiple sclerosis and ALS (Lou Gehrig's disease). People without disabilities working in mobile or harsh environments can also use WiViK with pen-based computers or touchscreens when standard keyboard input becomes difficult or awkward.

METHODOLOGY—WiViK has been designed in modules. A basic module supports the display of keyboards and selection with pointing devices. An additional module provides rate enhancement, including word prediction and abbreviation-expansion. A third module provides scanning access with 1 to 5 switches.

PROGRESS—In the past year, WiViK was upgraded and commercially released to work with Windows 95 as well as v. 3.1, and it has been translated into French. A number of incremental improvements that provide greater control of the interface are included. Updates take into consideration feedback from users. We are currently working on a major improvement to WiViK which will be a full 32-bit application for Windows 95 and NT. Modularity will also be enhanced in the future. Versions in foreign languages are also planned, including Japanese.

[152] WIVIK 2 SCAN: 1–5 SWITCH SCANNING ACCESS

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PURPOSE—WiViK 2 Scan is a module that adds switch-based scanning capabilities to WiViK 2 on-screen keyboard. This enables individuals who cannot use a keyboard or any pointing device to access a computer. Scanning involves the successive highlighting of items and selection by the activation of a switch when a desired item is highlighted.

METHODOLOGY—WiViK 2 Scan solves a particularly difficult problem of controlling Windows usually done with a pointing device such as a mouse. A typical solution is to emulate the mouse with a scanning mouse cursor. Our approach is to apply the scanning directly to the objects typically manipulated with the mouse: windows, menus, scroll bars, and other such objects. Menu choices are highlighted or scanned in succession. Similarly, the text cursor scans for easy editing. Future work will emphasize approaches that provide greater direct control and take better advantage of the users' skills, such as imprecise pointing.

PROGRESS—Three basic scanning methods are available using one to five switches: automatic, inverse, and directed. When automatic scan is selected, a highlight moves sequentially across successively smaller groups of items until the desired key is highlighted for selection. With inverse scanning, the highlight is moved manually by repeated or maintained switch activation. Directed scanning uses separate switches for each direction.

Automatic and inverse scanning support several patterns of movement. The function of each switch is individually adjustable in all methods, along with the speed of the moving highlight, to match the abilities of the user. Several keyboard layouts specifically designed for the various scan methods are available.

[153] KEYREP: WIVIK/KEYBOARD RATE ENHANCEMENT

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PURPOSE—The purpose of rate-enhancement software is to increase typing efficiency. Typing is relatively slow when using a single finger or stylus to type on a keyboard or when using WiViK. Two versions of software had previously been developed featuring word prediction and abbreviation-expansion: KeyREP (keyboard rate enhancement package) and WiViK 2 REP. Efforts this past year have been on merging these.

METHODOLOGY—When used with WiViK, predicted words are displayed within the WiViK window. When used standalone as in KeyREP, predicted words are displayed in a floating window and selected by typing a number key. Word prediction completes words that the user begins typing. Its frequency-of-use dictionary adapts to the user's writing style. Separate custom dictionaries are easily created by reading in the user's own files or from other sources such as Internet a great help when writing about specific topics. This also allows the creation of foreign language dictionaries. Dictionaries may be viewed or edited at any time.

Punctuation is handled intelligently. Spaces are automatically added after predicted words. Punctuation characters are positioned correctly and a space is automatically added when appropriate. In addition, following a period, question mark, or exclamation mark, the next letter typed is capitalized.

Abbreviation-expansion saves time by allowing frequently used words, phrases, sentences or other sequences to be replaced with abbreviations. Typed abbreviations are instantly converted into their corresponding, user pre-programmed expansion. All characters and functions of the standard keyboard may be used when creating expansions. Several sets of abbreviation-expansion may be created.

PROGRESS—In the past year, KeyREP was upgraded and commercially released to work with Windows 95 as well as v. 3.1. A further update is planned for spring 1997 to include a key new feature linking WiVox to provide auditory prompting of predicted words. The design for our next major release of KeyREP has also been completed. This future 32-bit application will include next word prediction and will fully integrate speech output. Research is underway to further enhance this tool to facilitate writing by new learners through appropriate queing and relevant dictionaries.

[154] WIVOX: VOICE OUTPUT FOR WINDOWS

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PURPOSE—WiVox provides auditory feedback of typing when using any Windows application. As a separate product it is intended to augment the standard visual presentation and enhance interaction by users who are learning to read or who have slight visual impairments. Wivox can also be used with WiViK and

KeyREP as a means to communicate through a computer. It is not a screen-reading package.

METHODOLOGY—WiVox provides a small on-screen window to turn speech on or off as required. When turned on, WiVox speaks the typed text. Choices may be made for speaking letters, words, partial words (up to the current character), complete sentences, or menus. WiVox also speaks text highlighted in any window. When used with the latest version of KeyREP, predicted words can be spoken as auditory cues.

A simple on-screen menu is provided for specifying the synthesizer and its settings. A word exceptions editor is included to allow the user to specify correct pronunciation of unusual or proper names.

PROGRESS—In the past year, ViVox was upgraded and commercially released to work with Windows 95 in addition to v 3.1, and support for software text-to-speech output through standard sound cards has been added.

FUTURE PLANS—WiVox will become closely integrated with WiViK and KeyREP as part of solutions-based packaging when new versions are released late in 1997. Example solution packages include: a writing aids package for users learning to read and write; an auditory scanning access package; and an augmentative communication package. Additional functions will be necessary to support these packages including auditory review of text for writing, and a pop-up window to quickly retrieve and output communication phrases.

[155] A BIOTELEMETRIC EMG TRANSCEIVER SYSTEM FOR ASSISTIVE DEVICES

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Sponsor: *None listed*

PURPOSE—The objective of this project is the design and construction of a wireless EMG transmitter and receiver system. Potential users of this device are people with ALS (Amyotrophic Lateral Sclerosis), and individuals with extremely limited muscle control. The transmitted EMG may be used for communications purposes or for device operation. Such a wireless link provides increased user mobility and improved user safety, resulting from removal of loose wiring, as well as improved cosmetic appearance, leading to better user acceptance.

PROGRESS—This project is at the stage where the hardware components required have been identified. Two designs have been produced, the first using analog, and the second digital, modulation techniques. Based on an investigation of each design's feasibility within power and size constraints, one design will be prototyped. Other design specifications are transmission distance (3–5 m), and capability for additional EMG channels.

IMPLICATIONS—Wireless EMG transmitter systems previously designed have been fairly large and cumbersome. This transmitter's small size will be especially advantageous when used in rehabilitation applications. Possible future applications include modification for transmission of ECG, EEG, and other physiological parameters.

FUTURE PLANS—Additional issues to be resolved include safety and interference. Any possible health risks due to RF transmission (especially near the head) must be examined. Also, possible interference from sources such as cellular telephones, radios, and microwaves will be investigated. The fabrication of a prototype and clinical testing of the device will follow, once the above issues are solved.

D. Private and Public Programs

[156] VIOLENCE AGAINST WOMEN WITH PHYSICAL DISABILITIES

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Sponsor: *Centers for Disease Control, Atlanta, GA 30333*

PURPOSE—The purpose of this study is to identify and measure risk factors for secondary conditions brought on by violence in the lives of women with physical disabilities and to develop an intervention to reduce violence in their lives. The specific aims of this study are to evaluate the dynamics of violence against such women to determine risks and protective factors, barriers to seeking help, and the effectiveness of available interventions; develop and test the validity of an abuse assessment instrument designed specifically for these women, in comparison to standard abuse assessments; develop and pilot test an intervention for these persons that will decrease their risk of abuse; and disseminate information about this violence and our study to women with disabilities, programs for battered women, disability service providers, medical practitioners, and researchers.

METHODOLOGY—We shall recruit through the Houston Area Women's Center 15 women with physical disabilities who have successfully resolved physical or sexual abuse in their lives and conduct and analyze semi-structured interviews with them to identify the determinants of behaviors effective in resolving abusive relationships and the helpfulness of available community resources. Then we shall develop and test an abuse intervention with a systematic process called Intervention Mapping. Through this process, we will develop a screening tool to identify abused women with disabilities that is based on existing instruments. We shall test this tool for reliability and validity on a sample of 438 women with disabilities recruited through the chronic care clinics of the Harris County Hospital District and Baylor College of Medicine.

PROGRESS—This 3-year project has just begun. Recruitment of participants is underway, and staff have been participating in abuse awareness training at the Houston Area Women's Center.

[157] BREAST CANCER SCREENING AMONG WOMEN WITH DISABILITIES

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PURPOSE—The purpose of this project is to explore, through a series of focus groups, the nature of perceived risk for breast cancer, concerns associated with mammography screening, preventive orientation, and environmental barriers to participation in mammography screening among women with disabilities aged 40 and older. The information obtained will be used to develop a model for predicating screening among this population and suggest strategies for preventive interventions.

METHODOLOGY—Women with a variety of physical disabilities will be recruited for focus group participation to discuss concerns associated with mammography screening, including environmental barriers they have encountered.

PROGRESS—This project begins fall 1997.

[158] HEALTH PROMOTION FOR WOMEN WITH PHYSICAL DISABILITIES

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Sponsor: *National Institutes of Health, Bethesda, MD 20892*

PURPOSE—The purpose of this project is to develop an intervention to enhance wellness among women with disabilities, one based on expanded theoretical models and measures of health-promoting behaviors that accommodate some of the circumstances of this population. Segments of this population are at a higher risk for certain acute and chronic conditions. They often have limited access to preventive health services and face negative social attitudes toward their potential for fitness and wellness, and they tend to have reduced motivation affecting health-promoting behaviors. The specific aims of this study are to identify the psychological, physical, social, and environmental factors that contribute to health-promoting behaviors of this population, develop and test methods for measuring their health-promoting behaviors and attitudes toward them, develop and pilot-test an intervention to inform and motivate such women to take action to improve their psychological, social, and physical health, and develop and pilot-test a theory-driven, multicomponent program to promote wellness among this population that targets increased self-efficacy related to health-promoting behaviors.

METHODOLOGY—To accomplish the aims of this study, we began with qualitative focus groups and individual interviews to understand how such women define wellness and practice health-promoting behaviors.

PROGRESS—Results have been analyzed from the focus groups and individual interviews and, based on these findings, a health promotion model has been developed that is guiding construction of the questionnaire. More than 200 participants have been recruited nationally to date. Development of the survey is underway. The content and format of the newsletter has been developed.

FUTURE PLANS—In the next phase, we shall establish a baseline of the perceived health status, health-promoting behaviors, and stage of change of a sample of 400 women with a range of physical disabilities and severity levels. We will then develop a motivational intervention of a newsletter, a wellness hotline, a fax-on-demand service, and a home page on the World Wide Web, to offer information and encourage action for women who may be in early stages of change or believe that their disability prevents them from engaging in health-promoting activities. In the final phase, we will develop and test the feasibility of a wellness action group program that will focus on individualized goal-setting, peer support, and enhanced self-efficacy for pursuing healthier living.

[159] REDUCING RISK FACTORS FOR ABUSE AMONG LOW-INCOME, MINORITY WOMEN WITH DISABILITIES

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Sponsor: *National Institute on Disability and Rehabilitation Research, Washington, DC 22202*

PURPOSE—The purpose of this project is to identify risk factors for emotional, physical, and sexual abuse experienced by women with disabilities and to develop and test strategies for reducing those risk factors, particularly among those from low-income, minority backgrounds where the incidence of abuse is the highest. In developing program models for reducing the risk of abuse of such women, it is important to consider cultural attitudes toward violent behaviors and family values. Another critical issue is the woman's perception of her situation and her readiness to seek help. In this project, we will pursue strategies to reach these women at all stages of change in resolving abusive situations. We will work not only with programs that help battered women, but also those that have contact with disabled women in various community contexts.

METHODOLOGY—We will pursue a broad-based program of training and dissemination activities to increase the capacity of communities to assist this population in abusive situations. By targeting community-based organizations, disability service programs, and the media, we hope to reach persons who may not realize that they are in abusive situations or who may never have contact with battered women's programs. By offering training to disability-related service providers on how to recognize and assist women in abusive situations, and to battered women's programs on how to meet the needs of their participants with disabilities, we hope to expand the resources available to women trapped in abusive situations.

PROGRESS—A written survey on abuse and women with disabilities was developed and sent to vocational rehabilitation and independent living service providers across the country; more than 600 of them responded, and the data have been analyzed. A written survey of programs delivering abuse intervention services to this population has been developed and will be sent to programs specializing in abuse intervention across the country.

FUTURE PLANS—A directory of programs delivering abuse intervention services to women with disabilities will be developed.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Prevalence of abuse of women with physical disabilities. Young ME, Nosek MA, Howland C, Chanpong G, Rintala DH. Arch Phys Med Rehabil 1997;78(12 Suppl 5):S34–8.

Sexual abuse and people with disabilities. Nosek MA, Howland C. In: Alexander CJ, Sipski ML, editors. Sexual function in people with disability and chronic illness: a health professional's guide. Gaithersburg, MD: Aspen Publishers, Inc.; 1997. p. 577–94.

[160] MANAGED CARE EXPERIENCES OF PERSONS WITH PHYSICAL DISABILITIES

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Sponsor: *National Institutes of Health, Bethesda, MD 20892*

PURPOSE—The purpose of this study was to examine the experiences of individuals with disabilities in managed care organizations (MCOs).

METHODOLOGY—Sixteen individuals with various physical disabilities, who had received health care in a health maintenance organization (HMO) or a preferred provider organization (PPO) participated in open-ended, qualitative interviews. They were asked a variety of questions about their experiences with their primary care physicians for any disability-related illnesses, such as how the managed care organization handled their care, the effectiveness of their primary care physicians, their ability to get referrals to specialists, denials of beneficial treatment and communication problems between their primary care physicians and specialists. All interviews were transcribed and analyzed using a software program called QSR NUD*IST to generate a system of topics from the text of the interviews.

RESULTS—A majority of those interviewed said they joined an MCO because of employer requirements or lower out-of-pocket costs. Participants were pleased with the low cost of included medications and preventive care such as mammograms, pap smears, and general checkups. They reported difficulty in making appointments and were not satisfied with the brief length of primary care physician office visits. They also reported not getting referrals to specialists at all or within a reasonable time and finding inaccessible equipment in providers' offices. Those reporting the most success in getting necessary treatment were those who could pay expenses out of their own pockets, those who had additional insurance through other family members, and those who were able to obtain additional services through state agencies and charitable clinics. Individuals with years of experience in working within a managed care system or who were skilled in advocating for their own health care needs were also more satisfied with their HMOs and PPOs.

VIII. Muscles, Ligaments, and Tendons

A. Muscles

[161] AUTOMATIC DECOMPOSITION OF THE ELECTROMYOGRAM

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PURPOSE—The electromyogram (EMG) is the electrical signal recorded by needle or surface electrodes during a muscular contraction. Interpretation of the EMG is an important part of the diagnostic evaluation of patients with suspected neuromuscular disorders. EMG signals are made up of discharges of groups of muscle fibers known as motor-unit action potentials (MUAPs). The purpose of this project is to develop methods for estimating physiological characteristics of muscle and nerve from EMG signals and MUAP waveforms. Such methods are expected to make EMG examinations more objective, reproducible, and diagnostically sensitive.

METHODOLOGY—EMG signals were recorded using needle electrodes from brachial biceps, anterior tibial, and first dorsal interosseous during moderate voluntary contractions in control subjects. The signals were decomposed into their constituent MUAPs using computer-aided decomposition as described below. In addition, MUAPs and compound muscle action potentials (CMAPs) were recorded using surface electrodes from intrinsic hand muscles in response to electrical stimulation at the wrist. Computer simulations were used to analyze the MUAP and CMAP waveforms in terms of the following parameters: the dispersion of the arriving nerve volley, the shape and duration of the intracellular action potential, the muscle-fiber conduction velocity, the distribution of muscle-fiber semilengths, and the location of the recording electrodes.

PROGRESS—We have developed three methods for estimating MUAP properties from EMG signals. *Spike analysis* uses statistical techniques to estimate the number of active motor units and their mean discharge rate. *Automatic decomposition,* intended for routine clinical use, uses pattern recognition techniques to estimate MUAP waveforms and discharge rates, but not complete discharge patterns. *Computer-aided decomposition,* intended for research use, allows interactive identification of complete motor-unit discharge patterns.

RESULTS—Our results show that CMAP and MUAP shapes are determined by anatomical as well as physiological factors. CMAPs and MUAPs (both surface-and needle-recorded) can be divided into four parts corresponding to four stages of electrical activity in the muscle: 1) the rising edge corresponds to the initiation of the action potential at the endplate; 2) the spike corresponds to the propagation of the action potential along the fibers; 3) the terminal phase corresponds to the termination of the action potential at the muscle/tendon junction; and 4) the slow afterwave corresponds to the negative afterpotential of the action potential. Based on these findings, we have developed new, noninvasive techniques for measuring the dispersion of motor-nerve conduction velocities and the muscle velocity recovery function.

FUTURE PLANS—The next phase of this project will investigate motor-unit discharge patterns in patients with post-stroke hemiplegia. We hypothesize that weakness associated with hemiplegia is due in part to an inability to recruit motor units and drive them at normal discharge rates.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Anatomical and electrophysiological determinants of the human thenar CMAP. Lateva ZC, McGill KC, Burgar CR. Muscle Nerve 1996;19:1457–68.

Decomposition of the compound muscle action potential into source and weighting functions. McGill KC, Lateva ZC. Proceedings of the 18th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; 1996;938.

Estimation of the compound intracellular action potential from surface-recorded muscle signals. Proceedings of the 18th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; 1996;937.

[162] PHYSIOLOGICAL BASIS OF STRENGTH FOLLOWING SURGICAL TENDON TRANSFER

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A745-2RA)*

PURPOSE—The purpose of this project is to understand the biomechanical design of the human wrist. We are using intraoperative sarcomere length measurements to not only validate and refine the experimental model, but to provide concrete guidelines for surgeons performing such procedures.

METHODOLOGY—Sarcomere length was measured intraoperatively in five patients undergoing tendon transfer of the flexor carpi ulnaris (FCU) to the extensor carpi radialis longus (ECRL) for radial nerve palsy. All measurements were made with the elbow in 20° of flexion.

RESULTS—Prior to tendon transfer, FCU sarcomere length ranged from 2.84±0.12 μm (mean±SEM) with the wrist flexed to 4.16±0.15 μm with the wrist extended. After transfer into the ECRL tendon, sarcomere length ranged from 4.82±0.11 μm with the wrist flexed (the new longest position of the FCU) to 3.20±0.09 μm with the wrist extended, resulting in a shift in the sarcomere length operating range to significantly longer sarcomere lengths ($p<0.001$). At these longer sarcomere lengths, the FCU muscle was predicted to develop high active tension only when the wrist was highly extended. A biomechanical model of this tendon transfer was generated using normative values obtained from previous studies of muscle architectural properties, tendon compliance and joint moment arms. Predicted sarcomere lengths pre-and post-tendon transfer agreed well with intraoperative experimental measurements. Variation in FCU muscle length over the range 200 mm to 260 mm resulted in large changes in absolute peak moment produced as well as the angular dependence of peak moment. This was due to the change in the region of FCU operation on its sarcomere length-tension curve relative to the magnitude of the ECRL moment arm. These data demonstrate the sensitivity of a short-fibered muscle such as the FCU to affect the functional outcome of surgery. In addition, we demonstrated that intraoperative sarcomere length measurements, combined with biomechanical modeling provide the surgeon with a powerful method for predicting the functional effect of tendon transfer surgery.

RECENT PUBLICATIONS FROM THIS RESEARCH

Intraoperative measurement and biomechanical modeling of the flexor carpi ulnaris-to-extensor carpi radialis longus tendon tranfer. Lieber RL, Fridén J. J Biomech Eng. In press.

Intraoperative sarcomere measurements reveal differential musculoskeletal design of long and short wrist extensors. Lieber RL, Lung B-O, Fridén J. J Exp Biol 1997;200:19–25.

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Altered sarcomere length range after surgical tendon transfer of the wrist flexor. Lieber RL, Fridén J. Med Sci Sport Exer 1995;27:S226.

Unusual muscle sarcomere lengthening and shortening with elbow joint flexion. Lieber RL, Fridén J. Soc Neurosci Abstr 1995;21:552.

[163] REPEATABILITY OF ESTIMATES OF MYOELECTRIC SIGNAL VARIABLES AND PARAMETERS

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Sponsor: *Camera di Commercio di Torino; Fondazione Cassa di Risparmio and Compagnia di San Paolo di Torino; Fondazione S. Maugeri, Regione Piemonte; Italian Ministry for University and Scientific Research; European Concerted Action on Surface EMG for Non-Invasive Assessment of Muscles (SENIAM)*

PURPOSE—The variance of repeated measurements in control subjects is a factor conditioning clinical applications of surface EMG techniques and myoelectric manifestations of muscle fatigue. It is the purpose of this study to assess this variance and find the contributions due to repeated trials (same day), different days, and different subjects for either voluntary or electrically elicited muscle contractions.

METHODOLOGY—Repeated measurements of surface EMG variables have been performed on controls (3–5 times/day, 4–5 days for each of 10 subjects and for each protocol) in isometric conditions on the vastus medialis and the biceps brachii muscles. Mean and median spectral frequencies (MDF and MNF), average rectified and root mean square values (ARV and RMS), muscle fiber conduction velocity (CV), and the crosscorrelation coefficient (CC) between the two double differential signals used for the estimation of CV were computed every second during electrically elicited contractions either tetanic (stimulation frequency of 20 Hz) or single twitch (stimulation frequency of 2 Hz) lasting 30 s. The initial values of these variables and their rate of change (initial slope) versus time were computed for each of the 15–20 contractions produced by each subject. The Intraclass Correlation Coefficient and ANOVA were used to evaluate variability over trials, days, and subjects.

PROGRESS—The protocols based on electrically elicited contractions have been completed and involved the vastus medialis and the biceps. Those focused on voluntary contractions are underway.

PRELIMINARY RESULTS—During fatiguing stimulated muscle contractions (f=20 Hz), initial values were defined as the intercept at t=0 of a regression line or exponential curve and initial slope was the derivative of such line or curve at t=0. During single-twitch nonfatiguing contractions (f=2 Hz) the average value of each variable was computed over the 30 s of contraction. During fatiguing contractions the initial value of spectral variables appeared to be the most repeatable with ICC near 85 percent, while it was below 50 percent for all the other variables. The ICC of initial slope was 52 percent for spectral variables and below 30 percent for the others.

The ICC obtained from single-twitch contractions were near 60 percent, but the ICC of CV was found to increase to 82 percent if the electrode location was carefully chosen in order to obtain a CC value above 95 percent. In addition, results obtained with interelectrode distances of 10 mm were more repeatable than those obtained with 5 mm. Although the values of ICC may appear low in some cases, it should be kept in mind that tests were performed on controls, and the values of EMG variables were within a narrow range. It is concluded that estimates of muscle fiber CV obtained using single-twitch stimulation are comparable with those obtained from more painful and complex needle procedures and that a 10 mm interelectrode distance is preferable to 5 mm for muscles that are long enough.

Fatigue indices are not very repeatable, and their reliable estimates require methodological improvements.

FUTURE PLANS AND IMPLICATIONS—This work is being extended to voluntary contractions performed at 10, 30, 50, and 70 percent of the maximal voluntary contraction level. The biceps, as well as other muscles, are being investigated. We believe that the technique is very promising, but further work on normal and pathological cases is required to assess reliability and normal ranges before generalized clinical applications may be considered.

RECENT PUBLICATIONS FROM THIS RESEARCH

Repeatability of electrically evoked EMG signals in the human vastus medialis muscle. Merletti R, Fiorito A, Lo Conte L, Cisari C. Muscle Nerve. In press.

Evaluation of repeatability of surface EMG variables on biceps brachii. Dimanico U, Barra M, Bertone P, et al. Proceedings of the 14th International Congress of EEG and Clinical Neurophysiology; Florence, 1997.

[164] MODEL-BASED UNDERSTANDING AND TEACHING OF SURFACE EMG

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Sponsor: *Camera di Commercio di Torino; Fondazione Cassa di Risparmio and Compagnia di San Paolo di Torino; Fondazione S. Maugeri, Regione Piemonte; Italian Ministry for University and Scientific Research; European Concerted Action on Surface EMG for Non-Invasive Assessment of Muscles (SENIAM)*

PURPOSE—Clinical applications based on surface EMG techniques and myoelectric manifestations of muscle fatigue are conditioned by the availability of the knowledge necessary for the interpretation of these signals. Such knowledge is scarce and scattered. As a consequence these new techniques are often applied empirically, without proper background and training, and without awareness of their possibilities and limitations. It is the purpose of this work to develop and make available to the clinical community proper educational tools based on multimedia approach and suitable for self training and continued education.

METHODOLOGY—Two tools have been developed and provide the first half of the total educational package. The first tool is a mathematical model, operating with an easy graphycal interface under Windows (3.11 or 95), that allows the user to construct and activate the muscle the signals of which are to be studied. For each of the up to 100 motor units that may be simulated, the user specifies the number of fibers, their length, innervation and termination zones, the depth and size of the (circular) territory, the fiber orientation, and the conduction velocity (CV). The user then specifies the conductivities of the medium, the location and spacing of the surface electrodes, the modalities for estimating muscle fibers CV, other computational details and whether the simulated contraction is voluntary or stimulated (random or synchronized firing of the motor units). One of the following modes of operation is then selected: a) computation of signal variables, b) display of signals detected by the electrodes, c) display of one signal versus one model parameter, or d) display of a signal variable versus one model parameter. At this stage, the computational part of the model is initiated and the required output is generated, displayed graphically, and saved as an ASCII file for export. The model simulates each of the two depolarized zones of a muscle fiber as a current tripole and adds the contributions of all the tripoles for each discrete time value during the simulation.

The second tool is a traditional multimedia course organized in five sections on a) signal analysis, b) EMG signals, c) biophysics and detection, d) single motor unit signal, e) interference signal and compound action potential. After each section, questions and exercises are provided for self evaluation.

PRELIMINARY RESULTS—The model has been used for research and teaching. Among the many options is the investigation of the relationship between estimated and real variables (for example, CV), of effects not so easy to predict, such as the effect of tissue anisotropy, of eletrode-fiber misalignement. Other didactically interesting simulations concern the estimate of CV along the muscle length, crosstalk, and so forth.

FUTURE PLANS—The second half of the total educational package concerns more clinical and practical aspects, such as how and where to place the electrodes, how to measure force, single twitch response, and the like, how to associate these findings to pathologies, and how to use the model for clinical signal interpretation. The entire package will be made available on compact disk.

RECENT PUBLICATIONS FROM THIS RESEARCH

Model-based understanding and teaching of surface EMG. Granata A, Avignone E, Merletti R. Proceedings of the 14th International Congress of EEG and Clinical Neurophysiology; 1997 Aug; Florence.

A multimedia tool for teaching the electrophysiology and biophysics of surface EMG. Merletti R, Dimanico U, Emanville D. Proceedings of the 14th International Congress of EEG and Clinical Neurophysiology; 1997 Aug; Florence.

[165] EFFECTS OF INTRAMUSCULAR APONEUROTOMY AND RECOVERY ON PENNATE SKELETAL MUSCLE

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Sponsor: *Ciba-Geigy Jubileum Stiftung, Basel*

PURPOSE—Intramuscular aponeurotomy is used clinically both to lengthen muscle and to weaken overactive muscle. Little is known about effects on muscle physiology and mechanisms of muscle recovery after such a intervention. The purpose of this project is to evaluate acute and long-term effects and the mechanisms by which these effects are reached.

METHODOLOGY—The medial gastrocnemius muscle of three groups of Wistar rats (age 15 wks) was studied: length-force characteristics and muscle geometry were determined 6 wks after proximal aponeurotomy at 50 percent length and immobilization in maximal dorsiflexion (3 days); 6 wks after sham operation and identical immobilization and 6 wks of no special treatment (controls).

After determining length-force characteristics in the second and third groups, proximal aponeurotomy was performed to asses its acute effects.

PRELIMIMARY RESULTS—Acutely, proximal aponeurotomy (groups 2 and 3) caused tearing of the muscle endomysial network. This tear along muscle fibers increased progressively in length if the muscle was exposed to high active lengths, but remained incomplete. The distal part of the muscle is not connected anymore by its proximal aponeurosis to the origion, but neurovascular supply remained intact.

This caused a scaled length-force curve at approximately 55 percent (i.e., force decreased but length force curves normalized for force showed only minor changes). This is compatible with the observation that the distal part of the muscle, despite being active, contributes only little to the muscle force. After recovery, the length force curve of the first group shifted to higher muscle lengths (i.e., became longer), but optimum force recovered to values similar to controls. The severed ends of the aponeurosis were reconnected by new aponeurotic tissue. Some muscle fibers of the distal muscle part showed degenerative changes near their proximal end. Muscle geometry showed extensive alterations compared to controls.

IMPLICATIONS—Despite acute effect of decreased muscle force, aponeurotomy is an appropriate method for lengthening short muscles. Full recovery of maximal muscle force can be expected, but on the ascending limb force may be decreased because of shifts of the length force curve to higher lengths. This fact needs to be taken into account when muscle weakening is a major indication for surgery.

[166] MUSCLE CO-CONTRACTION: EFFECT ON INTRA-ARTICULAR CONTACT PRESSURE

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Sponsor: *Irvin Cahen Chair in Orthopaedic Research*

PURPOSE—Muscle co-contraction can change the anatomic relationsip between articulating surfaces, particularly in the knee joint. The purpose of this study is to study the effect of knee flexor and extensor co-contraction on the contact stress distribution of the tibio-femoral joint.

METHODOLOGY—Thin film pressure sensors are placed in both compartments of cadaveric knees with minimal soft tissue stripping. Tension in quadriceps and hamstrings are applied by a servo-hydraulic actuator, and changes in peak pressure, contact area, and mean pressure are computed and examined as fuctions of joint angle and muscle co-contraction

PROGRESS—To date, we have performed six experiments. Pending statistical analysis of the results, posterior shifts in the center of pressure with the addition of quadriceps tension can be found; these are partially offset with the addition of hamstrings tension. It also appears that the relative increase of peak pressure and mean pressure per unit of hamstrings tension is less than the increase in pressure due to tension of the extensor muscles.

[167] MUSCLE FIBER DAMAGE DUE TO ECCENTRIC CONTRACTIONS

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Sponsor: *National Institute of Arthritis and Musculoskeletal Disorders, Skin Diseases Muscle Biology Program*

PURPOSE—The purpose of these studies was to determine the timing of the loss in cytoskeletal desmin that was previously observed. Since cytoskeletal loss can result in myofibrillar disruption, we felt that understanding its timing would provide insights into the damage mechanism.

METHODOLOGY—Rabbit extensor digitorum longus (EDL) and tibialis anterior (TA) muscles were examined 5 min or 15 min after eccentric exercise and 1 hour or 1 day after 30 min of an eccentric exercise protocol (n=16 rabbits). Muscles were cyclically activated at 40 Hz for 400 ms (approximately 50 percent P_o) and allowed to relax for 600 ms over the treatment period. This stimulation frequency (40 Hz) was chosen based on motor unit studies, which demonstrated that at this frequency force decline was due to fatigue of the muscle fibers themselves and not the neuromuscular junction or motor nerve. The frequency was also chosen to produce the force level observed during moderate intensity exercise. We also eccentrically exercised the slow soleus muscle and measured contractile and structural parameters.

RESULTS—The earliest change noted was a significant loss of desmin labeling in 2.5±0.63 percent of the rabbit extensor digitorum longus muscle (EDL) muscle fibers ($p<0.005$) 5 min after initiation of eccentric exercise. Some loss of tibialis anterior (TA) fiber desmin was also apparent at this time period (0.24±0.19 percent), but the magnitude was not significantly different from zero ($p>0.2$). Fifteen min after initiation of exercise, desmin loss was more pronounced, increasing to 7.4±1.4 percent and 4.6±1.0 percent in the EDL and TA, respectively ($p<0.005$). Finally, 1 day after 30 min of eccentric exercise the percentage of fibers without desmin staining rose to 23.4±3.7 percent and 7.7±2.4 percent in the EDL and TA, respectively ($p<0.001$). Loss of desmin staining occurred in the absence of contractile or metabolic protein disruption. Increased staining intensity of the intrasarcomeric cytoskeletal protein titin and an inability to exclude plasma fibronectin was also observed in most but not all fibers which had lost desmin staining. Desmin disruption thus represents a very early structural manifestation of muscle injury during eccentric contraction. Soleus muscles showed no such abnormalities. Soleus muscle stiffness decreased by only 30 percent over the 30 min treatment period while isometric force decreased by 85 percent. These data indicate that, while soleus muscles decreased their force generating capability significantly, there were a number of cross-bridges still attached that were not generating force.

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[168] SURFACE AND WIRE EMG CROSSTALK IN NEIGHBORING MUSCLES

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PURPOSE—EMG crosstalk between neighboring muscles presents a long-standing controversy without final conclusion as to its existence and, if so, to the mechanism underlying the process. We set an experimental protocol to clearly delineate whether crosstalk exists and under what circumstances.

METHODOLOGY—We undertook an investigation in animal model in which the muscle nerves of the soleus, medial, and lateral gastrocnemius, and tibialis anterior muscles were supramaximally stimulated while surface and wire EMG from all the muscles were recorded. Later, the muscle nerves were all cut, except for the nerve to the medial gastrocnemius, which was supramaximally stimulated while surface and wire EMG from all the muscles were recorded. Any EMG in the muscles in which their nerves were cut was considered pure and true crosstalk.

RESULTS—It was shown in a cat model that the extent of the crosstalk in the soleus, tibialis anterior, and the lateral gastrocnemius was less than 4–5 percent during maximal stimulation of the medial gastrocnemius when recording with surface electrodes. When recording with wire electrodes, the crosstalk was limited to 1–2 percent of maximal EMG activity in the corresponding muscles.

In several animals with a confirmed fat layer over the muscles, the crosstalk values in the inactive muscles ranged between 16–32 percent, suggesting that adipose tissue is responsible for inducing significant crosstalk in surface recordings of the EMG. There was no impact on the wire recordings.

It was concluded that when using electrodes appropriately sized to the muscle dimensions and correctly placed, the amount of crosstalk in surface and wire recordings is negligible. However, when recording surface EMG from muscles covered with adipose tissue, the EMG will be contaminated with significant crosstalk and may lead to false conclusions.

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Motor unit recruitment strategy of antagonist muscle pair during linearly increasing contractions. Bernardi M, Solomonow M, Baratta RV. EMG Clin Neurophysiol 1997;37:3–12.

[169] CONTROL OF JOINT MOTION WITH SYNERGISTIC STIMULATION OF ITS AGONIST/ANTAGONIST MUSCLES

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PURPOSE—Joint motion requires complex and simultaneous activation levels from the agonist and antagonist muscles in order to accomplish the intended task, while subject to various internal and external disturbances. This project initiated trials using antagonistic stimulation of the muscle groups crossing the joint with various levels of weighted motor unit recruitment in the agonist and antagonist to reaffirm our data collected from the elbow joint of humans. The objective was to improve the external control of a joint with regard to various loading conditions.

METHODOLOGY—Agonist/Antagonist muscle coactivation strategies were implemented through electrical stimulation. These strategies were based on the compromise between the physiological need for joint stabilization by the antagonist at high force levels and the need to prevent joint laxity at low force levels. These two conflicting requirements resulted in two coactivation parameters. The first, antagonist gain, was the linear gain of the antagonist muscle with respect to the input command. This parameter came into play when high net joint torques were called for. The second parameter, overlap, was a range of crossover of the antagonist unto the agonist domain. Strategies combining antagonist gain and overlap were tested as to their ability to track linear, step, sinusoidal, and pseudo-random input signals.

RESULTS—It was found that moderate amounts of antagonist gain (5 percent) and overlap (25 percent) would provide optimal tracking and minimal distortion during isometric and various types of load-moving contractions. When controlled by these strategies, the dynamic frequency response of the cat ankle joint showed small yet statistically significant differences on the dynamic response of the agonist/antagonist muscle-joint system.

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Evaluation of isometric antagonist coactivation strategies of electrically stimulated muscle. Zhou B-H, Baratta RV, Solomonow M, Olivier LJ, Nguyen G, D'Ambrosia R. IEEE Trans Biomed Eng 1996;43:150–60.

[170] THREE-DIMENSIONAL DESCRIPTION OF MUSCLE PROPERTIES

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PURPOSE—Traditional descriptive models of muscle properties are limited to the length-tension relationship obtained from isometric contractions, and from force-velocity curves obtained from isotonic contraction. Unfortunately, combining both curves to yield the force-length-velocity relationships is invalid, as data obtained in isometric contractions could differ by as much as 50 percent from those of shortening contraction. This problem was solved by describing length-force and velocity in a load-moving contraction.

METHODOLOGY—We have set up a protocol by which a muscle was stimulated electrically through its nerve, allowing shortening while applying displacing loads of different size. The initial length of the muscle when loaded and the final length after supramaximal stimulation provided a set of points with which the passive and total length-load (force) ratios were plotted as a function of load values. The shortening curve of the muscle during stimulation was recorded and differentiated mathematically to yield its velocity at any given length and for any given load, thereby allowing the construction of a load-length-velocity curve.

RESULTS—The initial results provide the first valid description of load-length-velocity of an isolated muscle, which could be used in large-scale modeling of human movement, neuroprosthesis design, and general understanding of muscle functions.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[171] LATERAL OR MYO-FASCIAL FORCE TRANSMISSION IN SKELETAL MUSCLE

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PURPOSE—Experiments on single myofibers and small bundles of myofibers indicate that lateral force transmission can take place. On the basis of morphological studies of 'in-series fibered muscle' and biomechanical modeling, it has been argued that force could also be transmitted laterally from the tapered ends of myofibers onto paired myofibers via the intramuscular connective tissue component. Shearing of the interfaces between myofibers is hypothesized to be the mechanisms of transmission. The interfaces are made up of basal membranes of both myofibers and their common endomysium.

The purpose of this project is to study the functional importance of such effects in fully activated whole muscle.

METHODOLOGY—Gastrocnemius medialis and EDL muscle of Wistar rats were studied: length force characteristics and muscle geometry were determined. The morphology of EDL muscle allows interference with myotendinous force transmission for selected parts of the muscle by performing distal tenotomy. Aponeurotomy allows interference with the inter fiber interfaces.

PRELIMIMARY RESULTS—It is estimated that by tenotomy of head II, III, and IV, up to 55 percent of the physiological cross-sectional area is prevented from using myotendinous force transfer.

The decrease in force is always considerably less than 55 percent. For example, optimum force decreased to 84 percent of whole muscle optimum force, as optimum length shifted by 1.6 mm to higher muscle length. The shift of optimum length is compatible with changes of estimates of active fiber length. Interference with interfiber interfaces decreased lateral force transmission in proportion to the magnitude of interference, but did not fully eliminate it.

IMPLICATIONS—These results show the importance of lateral force transfer from myofibers in whole muscle to the intramuscular connective tissue. So, in fact, two parallel paths for force transfer are available: myotendinous and myo-fascial transfer. Regarding myofascial force transfer, the possibility has to be considered that force will be transmitted from the muscle by other than myotendinous paths.

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[172] ISOMETRIC LENGTH-FORCE CHARACTERISTICS OF PENNATE MUSCLES DURING AND AFTER SHORTENING: EXPERIMENTAL AND MODELING RESULTS

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PURPOSE—The purpose of this project was twofold: to study effects of shortening history on isometric length-force curves of pennate muscle by experimental and modelling approaches, and to study muscle geometry and its functional effects by planimetric and finite element modelling (FEM).

METHODOLOGY—Variables of muscle geometry (i.e., fiber length, aponeurosis length, and fiber and aponeurosis angles), were determined during maximal activation. Isometric length-force curves were determined without previous shortening and after shortening over different length ranges at a number of shortening speeds. A descriptive model was designed to account for these effects.

An FEM was constructed that takes into account muscle fiber properties as well as aponeurosis and tendon properties and the mechanical interaction of these variables.

RESULTS—After previous shortening, length-force characteristics of maximally active rat medial gastrocnemius muscle differ very substantially from that determined in fully isometric contractions. Particularly at lengths at or over optimum length attained after low-speed shortening, muscle force is decreased compared to the fully isometric case. Actual isometric length-force properties can be constructed by connecting points of different curves according to shortening history. Negative length-force slopes found in the fully isometric condition are not present at lengths well over optimum.

FEM shows that a secondary distribution of mean fiber mean sarcomere length develops on activation through mechanical interaction of fibers and elastic components. FEM could not predict well either fully isometric or shortening history influenced length force curves, due to a primary distribution of fiber mean sarcomere length. However, FEM showed mechanisms of interaction between adjacent bundles of fibers within a muscle leading to secondary distributions of fiber mean sarcomere lengths. Indications for lateral force transfer from myofibers were also found.

IMPLICATIONS—Due to alterations of length-force curves, it is not appropriate to consider actual force delivered by a muscle as a result of combination of a fully isometric length force-curve and a force-velocity curve.

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A linear description of shortening induced changes in isometric length force characteristics of rat muscle. Meijer K, Grootenboer HJ, Koopman HFJM, Huijing PA. In: Boom HBK et al., editors. Proceedings of the 18th annual international conference IEEE: Engineering in Biology and Medicine Society; 1996, Amsterdam. New York: IEEE Publishing Service; 1996. p. 491–2.

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[173] SKELETAL MUSCLE LENGTH-FORCE CHARACTERISTICS DURING MAXIMAL AND SUBMAXIMAL ACTIVATION

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PURPOSE—The purpose of this project was to make a link between the results of experiments studying muscle properties under maximal activation and the *in vivo* properties of muscle that are rarely characterized by maximal activation. For that purpose several conditions of submaximal activation were imposed on *in situ* muscles for a systematic analysis.

METHODOLOGY—In addition to variables of muscle geometry (i.e., fiber length, aponeurosis length, and fiber and aponeurosis angles), the number of sarcomeres in series within fibers and filament-length parameters were determined. Submaximal activity of was induced in two ways: 1) in fully recruited muscle: stimulation frequencies between 100 and 15 Hz were imposed. This was performed for constant frequency (CSF) or decreasing frequency (DSF) protocols. A Hill-type model was constructed based on 100 Hz length force characteristics and force-frequency characteristics to describe length-frequency-force results for DSF protocols.

RESULTS—Length-force characteristics of submaximally active rat medial gastrocnemius and EDL muscle differ very substantially from that of the maximally active muscle. With all motor units active, force decreased at lower stimulation frequencies and muscle optimum length shifted to higher muscle lengths. If the low stimulation frequencies followed higher ones (history effects), the decrease in force was smaller (i.e., potentiation occurred). The shift of optimum length was also smaller in this case. Comparison of the model and experimental results show that these effects of stimulation history are quite specific for different DSF protocols.

IMPLICATIONS—Length-force and force velocity properties of submaximally active muscle are likely to be very much dependent on the degree of activation and its short time history. In effect, it creates the need for a control which may referred to as intramuscular coordination. For functional electrostimulation, these findings will have important implications, as well as for modelling of muscle and movement.

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B. Ligaments and Tendons

[174] MODELING TENDON DEVELOPMENT, ADAPTATION, AND REGENERATION: A PILOT STUDY

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PURPOSE—Tendon healing typically occurs through a process involving scar tissue, producing a structure with inferior mechanical properties compared to normal tendon. The long-term objective of this project is to develop a biomechanical framework for understanding how to promote better repair, resulting in a repaired or regenerated tendon having improved mechanical properties.

The specific objective of this pilot study is to answer three key questions:

1. How do composition, ultrastructure, and size affect the mechanical properties and strength of a tendon?
2. How does mechanical loading influence composition, ultrastructure, size, and mechanical properties?
3. How does age affect a tendon's response to mechanical loading?

METHODOLOGY—In this study we used a microstructural model to characterize soft tissues, such as tendon and ligament. This model uses mixture theory to represent collagen fibers embedded in a ground substance. We also used a phenomenological model to predict tendon mechanical properties and strength, based upon tendon age and mechanical loading history.

PROGRESS—We have successfully developed a microstructural model for uniaxial tensile and fatigue behavior of a wide range of soft skeletal connective tissues including tendon, ligament, meniscus, and articular cartilage. In addition, we have developed an analytical framework for describing changes in uniaxial tendon properties in response to the mechanical loading history as represented by a daily strain stimulus.

RESULTS—Our microstructural model produces stress-strain curves that closely resemble the curves obtained from mechanical testing, including the nonlinear toe region, linear elastic, and failure regions. The results of our phenomenological model focusing on growth, development, and adaptation of tendons to mechanical loading histories shows how tendons and ligaments achieve a desired stiffness by adjusting both their size and material properties during normal growth and under conditions of increased and decreased loading. These two models are providing new insights into previous experimental studies, and we plan on using these models to suggest new and improved clinical techniques for tendon repair and regeneration.

RECENT PUBLICATIONS FROM THIS RESEARCH

A computational model for loading-dependent growth, development, and adaptation of tendons and ligaments. Wren TAL, Beaupre GS, Carter DR. J Biomech. In press.

A microstructural model for the tensile constitutive and failure behavior of soft skeletal connective tissues. Wren TAL, Carter DR. J Biomech Eng. In press.

[175] LIGAMENTO-MUSCULAR PROTECTIVE REFLEX IN THE KNEE, SHOULDER, ANKLE, AND ELBOW

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PURPOSE—The ligaments are considered to be the primary restraints of a joint, keeping the bones aligned in their natural kinematic state throughout the range of motion. A growing pool of evidence shows that the musculature significantly contributes toward joint stability as well as protection of the ligaments. Our early work with the anterior cruciate ligament (ACL) shows the variety of mechanoreceptors present in this ligament, and also that a reflex arc exists from these mechanoreceptors to the muscles crossing the knee. Strain applied directly to the ACL resulted in reflex contraction of the hamstrings in animal models and in humans. We investigate whether such a protective reflex exists in other joints.

METHODOLOGY—We undertook several new studies to determine if such a ligamento-muscular reflex arc exists in other joints while stimulating articular nerve branches emerging from the ligaments. To date we have found that the protective reflex exists in the shoulder, elbow, and ankle, in addition to the knee.

RESULTS—Therefore, a synergistic relationship probably exists between the ligaments and muscles of every joint to ensure preservation of the tissue, prevention of damage, and proper kinematic alignment of the bones when various internal and external disturbing loads are applied. During surgery, the neural integrity of the ligament-joint should be preserved as much a possible in order to avoid joint arthropathy, and then utilized to design the appropriate postsurgical therapy.

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IX. Neurological and Vascular Disorders

A. General

[176] EFFECTS OF AGING ON MOTOR UNIT FIRING BEHAVIOR

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PURPOSE—It is hypothesized that there is a change in the control of aged motor units to accommodate their altered mechanical and physiological properties. The knowledge of age-related alterations in the control of motor units will provide insight into the observed decline in neuromuscular performance in the elderly.

METHODOLOGY—The first dorsal inter osseous muscle was chosen to be studied in male subjects during voluntary abduction of the index finger. Electromyographic signals, detected via the quadrifillar needle electrode and the surface bipolar electrodes, were recorded along with the force generated by the muscle. The Precision Decomposition Technique was used to identify firing times of motor units.

PROGRESS—Data from 10 ''young'' (20–37 yrs) and 10 ''elderly'' (65–88 yrs) subjects have been analyzed and the results compiled.

RESULTS—Observations on data analyzed so far suggest a depression of the firing rate of motor units in the elderly as compared to the young. The phenomenon of onion skin observed in the young whereby motor units recruited earlier during increasing force have a higher average firing rate than motor units recruited later which have a lower firing rate is not observed in the elderly, in whom the firing rate plots of motor units ''crossover.'' The highly correlated common fluctuations in the firing rates of concurrently active motor units in the young are not as correlated in the elderly. There are polyphasic and satellite motor unit action potentials observed in the elderly. Taken together, these observations suggest an altered control behavior of motor units in the elderly as compared to the young. Further testing of subjects and decomposition of data are in progress.

FUTURE PLANS—Further testing of subjects and analysis of data are in progress.

[177] MUSCLE STRENGTH AND FUNCTIONAL PERFORMANCE IN PARKINSON'S DISEASE: A PILOT STUDY

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PURPOSE—Our goal was to obtain a general indication of the severity of disability of persons with Parkinson's disease (PD). Qualitative clinical rating scales, such as the Hoehn & Yahr scale (H&Y) and the Unified Parkinson's Disease Rating Scale (UPDRS), are typically used. However, more precise and quantitative measurements may be desirable for evaluating disease progression and the results of clinical interventions. The purpose of this 1-year study was to gain more insight into the different characteristics of muscular strength and force production in relation to functional performance of persons with PD, so as to improve validity of clinical evaluations. Specific objectives are to develop an quantitative and reliable method to evaluate upper- and lower-body voluntary isometric and isokinetic (concentric and eccentric) strength of persons with PD; to correlate muscle strength parameters to gait performance and daily activity level for those persons; and to correlate scores on conventional PD clinical rating scales with the quantitative measures obtained for muscle strength and functional performance.

METHODOLOGY—Sixteen persons with PD were recruited from outpatient services at the Dayton VAMC and clinically rated using the H&Y and the UPDRS while being off medication. The subjects then performed a foot-tapping test to determine motor speed of both feet, and a sit-stand-walk test (SSW) to study complex motor performance and postural control. Within 2 weeks, the subjects underwent muscle strength (upper- and lower-body, concentric/eccentric/isometric) testing on an isokinetic dynamometer, and hand-grip strength testing with a hand-held dynamometer. Additionally, on a separate day, each underwent gait analysis using a 3-D motion capture system. Also, during one typical weekday, heart rate and body movements were monitored to estimate activity level and functional performance during daily life.

PRELIMINARY RESULTS—Data from 12 subjects have been analyzed. The H&Y was strongly related to UPDRS (r=0.86). None of these clinical ratings were significantly related to the muscle strength variables, the SSW, or activity level during daily life, and only moderately related to self-selected walking velocity (r=−0.64, r=−0.56) and stride length (r=−0.65, r=−0.57) as measured in the gait analysis. More strongly related to walking velocity and SSW performance was quadriceps concentric muscle strength (r=0.72, r=−0.60, respectively). Activity level was not significantly related to any variable. These data indicate that clinical ratings may only be moderately related to functional performance variables, such as the SSW, activity level during daily life, and gait parameters, suggesting a need for additional objective muscle strength and functional performance tests. The evaluation of the those with PD may be improved by the addition of quantitative muscle strength testing and functional performance analysis to the currently used qualitative clinical ratings.

[178] QUANTITATIVE MEASUREMENT OF UPPER LIMB SPASTICITY: A PILOT STUDY

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PURPOSE—A disabling aspect of central nervous system disease is spasticity, a velocity-dependent muscle hypertonus due to hyperactive stretch reflexes. This spasticity impairs self-care and mobility after spinal cord injury, multiple sclerosis, brain injury, and stroke. Clinical management of spasticity is often suboptimal in several ways: 1) impaired voluntary movement due to spasticity is difficult to distinguish from that due to weakness; 2) the development of spasticity cannot be prevented; 3) the relationship between spasticity and contracture is not well understood; and 4) spasticity treatments are often ineffective or too costly. A major hindrance to progress in these areas is lack of practical quantitative spasticity measures.

METHODOLOGY—In this study, we will develop a joint rotational device, patterned after the Lehmann-Price ankle device, for measuring spasticity during passive motion. We will also add two new measures to quantitate spasticity during active motion. We will then assess its test-retest reliability and validity in three groups of subjects: nondisabled controls, tetraplegic subjects with elbow extensor spasticity, and tetraplegic subjects with elbow flexor weakness. We expect to show that these new spasticity measures distinguish spastic tetraplegic subjects from controls and weak tetraplegic subjects.

The initial focus is to design an elbow joint rotational device that incorporates a computer-controlled torque motor for oscillating the elbow over 5° at varying frequencies from 3 to 12 Hz and that has sufficient torsional stiffness to avoid resonance effects in the frequency range of interest. The device includes transducers for monitoring torque and angular position during passive motion produced by the torque motor. Fourier analysis is applied to determine torque at the various applied frequencies and its phase relationship to displacement. The pathlength across oscillation frequency in the viscous stiffness and elastic stiffness plane is a reliable, valid measure of ankle spasticity, as shown by Lehmann and Price. In this study, we will assess reliability and validity of this pathlength measure for quantitating elbow spasticity. With the torque motor disengaged, two additional measures are derived to quantitate spasticity during active elbow movements.

FUTURE PLANS/IMPLICATIONS—This study undertakes to develop reliable, valid measures of elbow spasticity that can be used to guide clinical management with physical modalities, medications, and blocks.

[179] SIMPLE TWO-JOINT SYNERGY IN INDIVIDUALS WITH DOWN SYNDROME

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PURPOSE—Redundancy of motor control system is an important feature that the central nervous system successfully uses, based on priorities presently unknown. Motor patterns reflecting these priorities may be different in unimpaired adults and impaired individuals with changed biomechanics of the body (amputation), changed reflexes (spasticity), impaired decision making (Down syndrome), impaired preprogramming (Parkinson's disease), and so forth. The aim of this study was to investigate the organization of motor patterns in individuals with Down syndrome.

METHODOLOGY—Six individuals with Down syndrome and six age- and gender-matched controls sat comfortably in a chair, placed their right upper arm on an adjustable horizontal surface, and performed discrete elbow or wrist, flexion or extension movements in a sagittal plane under the instruction to move one of the joints as fast as possible. The hand was either pronated or supinated. The EMG activity of biceps, lateral head of triceps, flexor carpi radialis and extensor carpi ulnaris longus, as well as wrist and elbow joint angle changes in a sagittal plane, were recorded.

RESULTS—Control subjects and subjects with Down syndrome demonstrated qualitatively different EMG patterns in the flexor/extensor muscle pairs acting at the focal and postural joints when the instruction required moving only one joint (focal) of a two-joint limb segment. Controls use alternating, phasic bursts of muscle activation, apparently leading to a sequence of alternating flexion and extension torques around the joint. Down syndrome individuals use co-contraction of muscles acting at the postural joint, thus increasing its stiffness and decreasing its deviations in response to perturbations irrespective of their direction (pronation or supination). The co-contraction strategy apparently allows persons with Down syndrome to achieve satisfactory control over arm movements, although it is also likely to contribute to the general impression of clumsiness of their movements. The difference in the organization of the investigated simple synergy between control subjects and individuals with Down syndrome is likely to be secondary (adaptive) to the impairment in the ability of persons with Down syndrome to make quick accurate decisions.

FUTURE PLANS—It is quite possible that some atypical motor patterns, that may look ''clumsy,'' have been elaborated by the central nervous system of the individual with Down syndrome based on its current state and on the everyday experience with frequently occurring unexpected changes in motor tasks and movement conditions. Practice of movements in friendly, predictable laboratory conditions may lift some of the restrictions self-imposed by the central nervous system of the individual with Down syndrome and lead to more ''normal-looking'' movement patterns.

RECENT PUBLICATIONS FROM THIS RESEARCH

Organization of a simple two-joint synergy in individuals with Down syndrome. Aruin AS, Almeida GL., Latash ML. Am J Ment Retard 1996;101:256–68.

B. Swallowing Disorders

[180] SENSITIVITY AND SPECIFICITY OF A CLINICAL EXAMINATION OF SWALLOWING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C2113-RA)*

PURPOSE—The objective of this investigation is to develop a sensitive and specific clinical/bedside swallowing examination by testing the sensitivity and specificity of clinical/bedside appraisal procedures for dysphagia. We seek answers to two primary research questions: What is the sensitivity of a clinical/bedside examination for detecting dysphagia? What is the specificity of a clinical/bedside examination in the evaluation of dysphagia? Dysphagia is defined as the presence of bolus penetration/aspiration into the laryngeal vestibule during swallowing and/or the presence of a delayed initiation of swallowing.

METHODOLOGY—Subjects will be 180 clients in the VA Medical Centers in Nashville and Madison who have suffered a recent stroke prior to the time of examination. Each subject will receive a clinical/bedside swallowing examination and be rated for the presence of penetration/aspiration and/or delayed swallowing. A videofluoroscopic examination of swallowing will be conducted on each subject, and the presence of penetration/aspiration and/or delayed swallowing will be rated. Using the videofluoroscopic examination results as the gold standard for the presence of dysphagia, signal detection analysis will be conducted to determine the sensitivity and specificity of the clinical/bedside swallowing examination.

PROGRESS—The investigation will be initiated October 1997.

[181] EFFECTS OF AGE ON OROPHARYNGEAL SWALLOWING

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PURPOSE—The long-term objective of this work is to increase understanding of the effects of aging on swallowing physiology in an effort to advance the diagnosis and treatment of swallowing disorders in age-related disease. The short-term aims of this project were to establish a normative database of movement parameters comprising salient features of oropharyngeal swallowing in conjunction with structural brain quantification throughout the adult age interval of 45 to 95 years and to further develop a pressure transducer, designed to measure tongue strength during swallowing.

PROGRESS—We are grateful to Kay Elemetrics who supported our efforts to modify aspects of their

Swallowing Workstation, thereby resulting in our intraoral pressure measuring instrument. This is comprised of a thin strip of pressure-sensitive air-filled bulbs attached to the midsaggital line of the hard palate. The three pressure bulbs measure tongue strength simultaneously at anterior, mid, and posterior palate. Pressure from each bulb is transduced and recorded on the Workstation and linked with video data in order to facilitate understanding of amplitude by time relationships as they impact bolus transfer during swallowing. Prior to achieving the database of swallowing parameters, it was necessary to test the new instrumentation in order to determine the effect of its presence on swallowing physiology.

RESULTS—Principle components analysis of the submental EMG recordings of swallowing in bulb-in and bulb-out conditions indicated no significant systematic differences between conditions. The absence of a bulb condition effect indicates that swallowing physiology with the intra-oral pressure measuring instrument in place is similar to normal swallowing. We interpreted these findings as a green light to proceed with the new instrumentation as an integral part of our methodology. Significant differences in the EMG signal were found, however, for bolus viscosity (liquid/semi-solid) and age. Older subjects tended to have reduced EMG amplitude and a smaller range of phase shifts relative to their young counterparts.

While instrumentation development was underway, we used the Iowa Oral Performance Instrument (IOPI), a single air-filled pressure-sensitive bulb, to obtain maximum lingual pressures during isometric and saliva swallows in 15 old control, and 25 stroke, subjects. Performance on the isometric task did not distinguish control from stroke groups, nor did it differentiate stroke subjects from each other by site of lesion. However, stroke subjects showed a trend toward reduced swallowing pressures at the blade position ($p=0.07$). Also, stroke subjects who generated lower isometric pressures tended to have slower oral transit duration on videofluoroscopy.

Currently, we have collected multiple levels of data, including isometric and swallowing pressures, videofluoroscopic swallows, and magnetic resonance images (MRI) of the brain and the tongue on 51 of our intended 100 nonimpaired control subjects, stratified by age (45–95 years) and by gender. Preliminary analysis of six of the 45-year-olds and six of the 75-year-old controls reveals differences in swallowing duration, pressure generation, and clearance of material from the upper aerodigestive tract. Gender differences also are found in biomechanics of the volitional initial portion of the oropharyngeal swallow as well as for tongue volume as measured by the MRI. We shall continue data collection and analysis for the normative age- and gender-stratified swallowing database. It is of interest that several of our older controls (age>75) demonstrated aspiration of thin liquids during the study protocol. How this swallowing outcome relates to lingual pressures, timing, lingual volume, and central nervous system changes (the latter two variables measured with MRI) is currently under study.

Another aspect of our research is to apply the same instrumentation and protocol to stroke patients, with the intent of comparing physiologic and functional outcomes with those of the old controls. Therefore, we have collected analogous data on eight stroke patients, to date, for comparison to their age-matched controls.

Finally, this project permitted imaging of the esophagus on seven young and four old controls. Maximum distention of the UES, LES, and at 5 cm above the LES was measured, and speed from the upper esophagus to the LES for the head and tail of the bolus was analyzed. None of the anatomical or physiological parameters studied were significantly different between the two groups, indicating that the esophagrams of nonimpaired elders should appear similar to those of young adults, and abnormalities obtained from esophagrams most likely indicate specific pathologies in the elderly that must be carefully addressed.

FUTURE PLANS—In future, we intend to complete data collection and analysis for the normative age-stratified swallowing database that will improve clinical ability to differentiate pathologic from simple age-related changes in swallowing. Along with brain and lingual MRI analysis, this effort will elucidate underlying mechanisms in that central and peripheral nervous system contributions to changes in swallowing function with nonimpaired aging and with age-related disease will be determined.

We shall also pilot test a program in which old nonimpaired individuals who demonstrate reduced tongue volume (as determined by measuring volume on MRI) and perform on the lower end of the normal range for swallowing function in terms of strength (using our new intra-oral pressure instrument and the Kay Workstation), participate in an 8-wk lingual resistance exercise program.

RECENT PUBLICATIONS FROM THIS RESEARCH

Neurological diseases affecting oropharyngeal swallowing. Buchholz D, Robbins JA. In: Perlman A, Schulz K, editors. Deglutition and its disorders. San Diego, CA: Singular Publishing Group; 1997. p. 319–42.
Normal swallowing and aging. Robbins JA. Sem Neurol 1997;16:309–17.
Age effects on lingual pressure generation as a risk factor for dysphagia. Robbins JA, Levine RL, Wood J, Roecker E, Luschei E. J Gerontol Med Sci 1995;50A(5),M257–62.
Physiology of swallowing: protection of the airway. Martin B, Robbins JA. Sem Respir Crit Med 1995;16(6):448–58.
A penetration-aspiration scale. Rosenbek JC, Robbins JA, Roecker EB, Coyle JC, Wood JL. Dysphagia 1996;11:93–8.

[182] BIOMECHANICS AND SENSORY INPUT OF SWALLOW AFTER HEAD AND NECK CANCER

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PURPOSE—This project examines the biomechanical effects of head and neck treatment on swallowing function and on the individual's ability to exert voluntary control over specific aspects of the swallow as well as the impact of varying bolus flavor. A biomechanical analysis will enable us to define the changes in muscle pull created by head and neck surgical procedures and to develop more effective swallow interventions, including surgical reconstruction.

METHODOLOGY—Videofluoroscopic (VFS) swallowing studies of persons under treatment for head and neck cancer, collected 3 points in time post treatment, will be quantified temporally and biomechanically to identify the ways in which voluntary maneuvers and postures as well as heightened sensory input from bolus flavors impact the swallow, as compared to normal age- and gender-matched controls.

PROGRESS—Over the last 15 mo, we have established approval for use of human subjects at participating institutions, and trained clinicians at those institutions in the proper instruction, administration, and assessment of adequacy of postures and maneuvers. We have recruited head and neck cancer subjects and age- and gender-matched controls.

FUTURE PLANS—We seek to complete a study of the effect of a sour-flavored bolus in head and neck cancer subjects and to continue recruitment.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effect of a tongue holding maneuver on posterior pharyngeal wall movement during deglutition. Fujiu M, Logemann JA. Am J Speech-Lang Pathol 1996;5:23–30.
Effects of two breath-holding maneuvers on oropharyngeal swallow. Ohmae Y, Logemann JA, Hanson DG, Kaiser P, Kahrilas PJ. Ann Otol Rhinol Laryngol 1996;105:123–31.
Pharyngeal swallowing elicited by fluid infusion: role of volition and vallecular containment. Pouderoux P, Logemann JA, Kahrilas PJ. Am J Physiol 1996;270(Gastrointest Liver Physiol 33):G347–54.

[183] LONG-TERM SURVIVORS OF HEAD AND NECK CANCER

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PURPOSE—Our first hypothesis based on pilot data is that treated head and neck cancer subjects continue to suffer significant functional deficits long after treatment has been completed, and that the exact nature of these deficits will vary, based on the original tumor site and stage, and nature of treatment (surgery and/or radiotherapy). A second objective of this project is to evaluate the effects of a specific intervention strategy on subject function. Our third objective is to determine whether the gains are maintained long term. A fourth objective is to define the cost of the intervention proposed and the cost impact of the intervention, such as a reduction of the need for expensive prepared feedings, decreased incidence of hospitalization for pneumonias that may be aspiration-related or for depression related disorders due to speech and swallowing problems, and changes in other health care needs. A fifth and final objective of this proposal is to determine whether it is possible to predict from baseline measures, and disease stage and treatment variables, those subjects who will benefit most from the intervention.

METHODOLOGY—Data collection begins with a baseline collection period on 300 head and neck cancer subjects at least 1-year post treatment, after which we enter into the intervention stage of the protocol any subject who is not eating a full range of diet consistencies (i.e., liquid, paste and masticated materials) because of a swallowing disorder, or whose oropharyngeal swallow efficiency is 30 or less on any food consistency, randomizing them to early intervention (group A) or delayed intervention (group B). At the end of the 4-mo intervention period for Group A, all subjects will be retested and the change over the 4-mo period measured. After retesting of function, subjects in Group B will begin their 4-mo intervention protocol, while Group A will receive no intervention. At the end of the second 4-mo period, both groups will again be tested to identify the effects of intervention in B and the carry-over in A.

PROGRESS—Over the last 15 mo, we have recruited head and neck cancer subjects, sending letters to medical oncologists, radiation oncologists, otolaryngologist/head and neck surgeons, and speech-language pathologists throughout northern Illinois and Indiana. We have begun to get phone calls from these individuals regarding the project and referral of subjects.

We have completed an analysis of oral and oropharyngeal cancer subjects who received swallowing and speech therapy of various types. We examined the effectiveness of range of motion exercises versus a general therapy program and found that those subjects who had range of motion exercises were demonstrating significant improvements in both speech understandability and swallowing efficiency.

FUTURE PLANS—We seek to accrue head and neck cancer subjects and follow them for a year and to complete data reduction on these 150 subjects.

RECENT PUBLICATIONS FROM THIS RESEARCH

Speech and swallowing rehabilitation for head and neck cancer patients. Logemann JA, Rademaker AW, Colangelo LA, Pauloski BR. Oncology 1997;11:651–9.

[184] THE EFFECTS OF RADIOTHERAPY/CHEMOTHERAPY ON VOICE, SPEECH, AND SWALLOWING FUNCTION

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PURPOSE—This project proposes to define the effects of organ preservation protocols involving high dose radiotherapy (5,000+ cGy) with or without chemotherapy in 300 persons with oral, laryngeal, and pharyngeal cancer (previously untreated Stages II to IV disease) and to measure the effectiveness of swallow maneuvers in improving the swallow. Each individual's response to swallow maneuvers will be defined.

METHODOLOGY—Each subject will be followed for 12 mo after treatment completion. All will be studied pretreatment, and at 1, 3, 6, and 12 mo post completion of chemoradiotherapy. At each of these data collection points, each will receive a videofluoroscopic assessment of swallowing, a voice recording for acoustic analysis, and a speech analysis for understandability and articulatory production.

PROGRESS—Over the past 15 mo we have established approval for use of human subjects at participating institutions and trained clinicians at those institutions in the study protocol; and recruited head and neck cancer subjects.

RESULTS—Results continue to show a severe effect of combined high dose radiation and chemotherapy to the functions of laryngeal elevation and tongue-base/pharyngeal wall contraction. The combination of high-dose radiotherapy and chemotherapy appears to have a more devastating effect on swallowing than radiotherapy without concurrent chemotherapy. However, these are very early results and must be corroborated with larger subject numbers.

FUTURE PLANS—We seek to recruit 75 subjects and follow them for a year to complete data reduction on them, and to continue recruitment of head and neck cancer subjects.

RECENT PUBLICATIONS FROM THIS RESEARCH

Swallowing disorders in head and neck cancer patients treated with radiotherapy and adjuvant chemotherapy. Lazarus CL, Logemann JA, Pauloski BR, et al. Laryngoscope 1996;160:1157–66.

[185] THE EFFECTS OF SURGICAL INTERVENTION ON SPEECH AND SWALLOWING FUNCTION IN PERSONS WITH RECURRENT/RESIDUAL DISEASE

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PURPOSE—Changes in patterns of care over the past 5 years have resulted in the treatment of persons with oral and oropharyngeal cancer with radiation only or radiation and chemotherapy who would have previously received surgical intervention. It is expected that a number of these individuals will present with residual or recurrent disease for which surgery will be required for cancer control, and they may face significant functional impairment in the areas of speech and swallowing after salvage surgery. This study will examine the functional impairments and recovery of function experienced by this group over a 12-mo period after surgery.

METHODOLOGY—Each subject will be followed 12 mo postoperatively. All will be studied preoperatively, and at 1, 3, 6, and 12 mo posttreatment. At each of these data collection points, each subject will receive a videofluoroscopic assessment of swallowing and speech, an articulation test, and recording of conversational speech for later intelligibility rating.

PROGRESS—Over the last 15 mo, we have established approval for use of human subjects at participating institutions, and trained clinicians at those institutions in the proper instruction, administration, and assessment of adequacy of postures and maneuvers. We have recruited head and neck cancer subjects, and surveyed participants concerning changes in the pattern of care for recurrent subjects. We have modified the study protocol to include four groups of subjects, depending upon the combination of primary and salvage treatment, either of which may be radiotherapy, chemotherapy, or surgery.

FUTURE PLANS—We seek to reconceptualize the study questions for the new subject populations, to evaluate the revised protocol for accruals, retention, and potential for early stopping, and to continue recruitment of head and neck cancer patients.

[186] HEAD AND NECK CANCER: QUALITY OF LIFE, PERFORMANCE, AND PATIENTS' PRIORITIES

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PURPOSE—The specific aims of the project are as follows: a) to determine rate and degree of recovery of function, mood, and overall quality of life by group (site, treatment) and time since treatment; to identify times of greatest difficulty for subjects. b) to evaluate subjects' priorities with respect to potential disease and treatment sequelae; to determine whether these rankings change over time as subjects experience effects of disease and treatment; and to determine the relationship between priority rankings and actual function. c) to compare the priorities of subjects with head and neck cancer to nonimpaired controls.

METHODOLOGY—A total of 500 head and neck cancer subjects representing four treatment types will be assessed at four points in time, pretreatment, and at 3, 6, and 12 mo posttreatment. The assessment will consist of the PSS-HN (Performance Status Scale for Head and Neck Cancer), the FACT-HN (Functional Assessment of Cancer Therapy Scale-Head and Neck), the subject's Priorities Ranking Scale, as well as the collection of relevant medical, personal, and social demographic data.

PROGRESS—Over the last 15 mo, we have established approval for use of human subjects at participating institutions, and trained clinicians at those institutions in the proper instruction, administration, and assessment of adequacy of postures and maneuvers. We have recruited head and neck cancer subjects.

FUTURE PLANS—Data collection will continue, and we will work with speech-language pathologists to identify and resolve any issues that interfere with timely, accurate collection. A significant increase in accrual is expected when IRB approvals have been obtained for all participating institutions. As head and neck cancer subjects are more rapidly accrued, we will begin enrollment of the control group.

RECENT PUBLICATIONS FROM THIS RESEARCH

A longitudinal assessment of quality of life in laryngeal cancer patients. List MA, Ritter-Sterr CA, Baker TM, et al. Head Neck 1996;18:1–10.

[187] THE EFFECTS OF SURGICAL RECONSTRUCTION ON SPEECH AND SWALLOWING

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PURPOSE—This study examines the effects of surgical reconstruction for oropharyngeal cancer as a first line rehabilitation strategy for persons with oral cancer. It is our hypothesis that particular surgical reconstruction can facilitate speech and swallowing or cause a further decrement in function. This project will follow 8 groups of surgically treated oral cancer subjects to examine the effects of surgical reconstruction on early and late functional outcomes of speech and swallowing.

METHODOLOGY—Each subject will be followed for 3 months postoperatively. All will be studied preoperatively, and at 1 and 3 mo posthealing. Those reconstructed with flaps designated as sensate will receive an additional assessment at 12 mo posthealing. At each of these data collection points, each subject will receive a videofluoroscopic assessment of swallowing and speech, an articulation test, and recording of conversational speech for later intelligibility rating.

PROGRESS—Over the last 15 mo, we have established approval for use of human subjects at participating institutions, and trained clinicians at those institutions in the proper instruction, administration, and assessment of adequacy of postures and maneuvers. We have recruited head and neck cancer subjects.

RESULTS—Results showed that irradiated subjects had significantly reduced oral and pharyngeal swallowing performance, while speech performance was not impaired.

FUTURE PLANS—We seek to add three institutions where the surgeons specialize in sensate flap reconstruction, and to continue accrual of head and neck cancer subjects.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effects of intraoral prostheses on speech in oropharyngeal cancer patients. Colangelo LA, Pauloski BR, Logemann JA, et al. Am J Speech-Lang Pathol 1996;5(4):43–55.

Effect of intraoral prostheses on swallowing function in postsurgical oral and oropharyngeal cancer patients. Pauloski BR, Logemann JA, Colangelo LA, et al. Am J Speech-Lang Pathol 1996;5(3):31–46.

T stage and functional outcome in oral and oropharyngeal cancer patients. Colangelo LA, Logemann JA, Pauloski BR, Pelzer HJ, Rademaker AW. Head Neck 1996;18:259–68.

[188] 3-D CONTOUR TRACKING OF PHARYNGEAL BOLUS MOVEMENT USING A KNOWLEDGE-BASED SNAKE SEARCH ALGORITHM

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PURPOSE—Videofluorography (VFG) of the pharyngeal phase of swallowing using a barium-mixed bolus is in wide clinical use for assessing patients with swallowing disorders. VFG is usually done with both lateral (LA) and anterior-posterior (AP) views, most commonly in two separate sittings. It is important but tedious to reconstruct a real-time, three-dimensional (3-D) view of pharyngeal bolus evolution from these LA and AP video images. We applied a knowledge-based Snake search algorithm to semiautomate the contour tracking and reconstruction of these VFG images. 3-D evolution of the pharyngeal bolus can then be accurately and efficiently visualized.

METHODOLOGY—VFG of pharyngeal bolus transport in control subjects was recorded using barium-mixed boluses with combinations of three bolus consistencies (185, 5,000, 45,000 centi-poise (cp)), three bolus volumes (5, 10, and 20 cc), and three head positions (20° flexion, neutral, and 20° extension). VFG of a total of 16 barium swallows were recorded for each subject (8 in LA, 8 in AP). The resulting LA and AP video images were digitally captured and matched frame-by-frame on a Power Mac computer. A knowledge-based Snake search algorithm was used to generate points to satisfy both internal (i.e., smoothness) and external (i.e., boundary fitting) constraints. Using the points generated from the LA and AP video images, we traced the 3-D bolus movement at each time instant, assuming elliptic geometry of the cross-section area of the pharynx. By concatenating the 3-D images for each time instant, we developed a 3-D movie representing pharyngeal bolus movement.

PROGRESS—We have so far studied seven controls with normal swallow in pharyngeal phase.

PRELIMINARY RESULTS—VFGs of pharyngeal swallowing (viscosity: 185 cp, head position: neutral) in a control were analyzed with three bolus volumes (5, 10, 20 cc). Mean errors of the Snake algorithm were estimated to be 1.3 mm (in LA views) and 2.1 mm (in AP views) for all three volumes with respect to manually traced bolus boundaries. Bolus front and tail velocities were calculated from the original LA images and compared with those generated from the Snake search algorithm. Mean errors in bolus velocity calculation for all three bolus volumes were 5.8 cm/s (front), and 2.6 cm/s (tail).

IMPLICATIONS—3-D pharyngeal bolus movement can be traced both efficiently and accurately using a knowledge-based Snake search algorithm. Video images from standard clinical VFG studies for pharyngeal bolus transport can be fully utilized to understand swallowing disorders.

FUTURE PLANS—Analysis of all VFG studies (with various combinations of bolus consistencies, bolus volumes, and head positions) using Snake search algorithm are underway for all controls as well as for persons with various swallowing disorders.

[189] THE EFFECT OF BOLUS VISCOSITY ON THE PHARYNGEAL PHASE OF SWALLOWING: A STUDY USING COMPUTATIONAL FLUID DYNAMICS

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PURPOSE—Many factors affect laryngeal penetration during the pharyngeal phase of swallowing. The interplay of these factors cannot be thoroughly investigated using common clinical studies such as videofluorography (VFG). Therefore, there is significant limitation for utilizing VFG to derive guidelines for safe oral feeding. Modification of bolus consistency is a common clinical practice to ensure safe oral feeding, but the limitations of dietary modification and the reasons for its efficacy are not well understood. We propose to study the effect of bolus viscosity on the pharyngeal phase of swallowing using computational fluid dynamics based on Galerkin finite element analysis.

METHODOLOGY—We constructed a two-dimensional planar model using a computational fluid dynamics software, FIDAP. VFG images were obtained by having control subjects swallow 10 cc of barium-mixed boluses with three consistencies: measured viscosities (centi-poise)/densities (g/cc) of 185/2.84, 5,000/2.36, and 45,000/2.75, respectively. Digitized lateral VFG images from these controls were used to trace the pharyngeal wall motion that was implemented as boundary conditions in the simulation. The simulation was divided into two consecutive phases: 1) the filling phase when the bolus first enters into the pharynx, and 2) the moving boundary phase when pharyngeal peristalsis becomes a dominant force for the bolus transport.

PRELIMINARY RESULTS—Our simulations reveal that the bolus front in the low-viscosity fluid moves faster and breaks off more easily from the main bolus than in the mid- and high-viscosity fluids. Therefore, a low-viscosity fluid is more likely to reach the larynx before it can close. Recirculations form during the peristaltic transport of the low-viscosity fluid, but not when mid- and high-viscosity fluids are swallowed. These recirculations could contribute to laryngeal penetration in situations where they produce high velocities in the direction of the larynx. On the other hand, the simulation indicates that the pharyngeal muscles must generate a greater force to propel higher-viscosity boluses, and thus that persons with impairment of the muscles required to propel the bolus would do better with low-viscosity food. Simulations based on VFG data from a person with brain stem stroke and weakened pharyngeal peristalsis validate this hypothesis.

IMPLICATIONS—Persons with dysphagic often have the most trouble swallowing thin liquids, and their diets are commonly restricted to thick liquids, a practice that is supported by the modeling results. Pharyngeal bolus transport becomes 'viscous-dominant' when the Reynolds number (RE), an estimate of fluid inertial versus viscous forces, is less than one. No apparent additional benefit can be gained by further thickening of the bolus beyond this point. For individuals with reduced pharyngeal peristalsis, who often have impaired oral-tonsil control and delayed laryngeal closure, thickening of the diet should be kept to a minimum (i.e., maintaining RE close to one).

C. Vascular Disorders

[190] POLESTRIDING EXERCISE AND VITAMIN E FOR MANAGEMENT OF CLAUDICATION PAIN

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PURPOSE—Persons with atherosclerotic peripheral arterial disease (PAD) of the lower limbs are subject to periods of intermittent claudication, caused by the formation of atherosclerotic plaques which narrow or occlude arteries. This condition results in an inadequate blood flow causing ischemic muscle pain. If unchecked, progressive atherosclerotic disease in the leg arteries will result in tissue damage, ulceration, gangrene, and ultimately amputation. The purpose of this project is to determine the efficacy of utilizing Polestriding (PS), a form of walking that uses muscles of the upper and lower body in a continuous movement similar to cross country skiing, with and without vitamin E supplements for increasing exercise tolerance and management (delaying the onset) of intermittent claudication pain in subjects with PAD.

METHODOLOGY—This clinical trial utilizes a prospective, randomized two-by-two factorial design. Subjects are randomized into four groups after baseline testing is completed: PS with vitamin E, PS with placebo; vitamin E only, placebo only. A sample of 84 subjects with a current diagnosis of PAD, a history of intermittent claudication, and an ankle to brachial index (ABI) <0.85 at rest, and/or <0.60 after exercise are being recruited. Intermittent claudication pain must be the primary limiting factor to maximal exercise during the treadmill test.

Initially, all subjects complete a symptom-limited maximal wheelchair exercise test to screen for coronary artery disease, at least two symptom-limited ramp treadmill tests to establish a stable baseline, a constant load treadmill test, a segmental arterial examination, ABIs determined immediately before and after treadmill walking, Borg's ratio scale to determine subjects' perception of effort and severity of exercise induced claudication pain, a quality of life battery, and daily physical activity recall. Subjects are then randomized.

Those randomized into the PS group receive PS instruction and training; sessions include a 3–5 min warm-up, interval training, and cool down. Each subject's training program is individualized according to the results of the baseline exercise tests. Individuals in the vitamin E/Placebo-only groups come to the laboratory weekly for ABI measurements, and physical activity recall. The walking endurance treadmill test, constant load treadmill test, segmental arterial exams, quality of life testing, and physical activity recall interviews are repeated on all subjects at specified intervals.

PROGRESS—Eighteen males (mean age=61±8 non-PS, 66±8 PS) have been randomized thusfar. Subjects are educated (12 yrs school completed) and moderately obese (body mass index =32.8±5.9 non-PS, 28.6±4.9 PS). Prevalent comorbidities and risk factors include arthritis, hypertension, and smoking. Subjects report that they are able to walk one to two blocks before the onset of claudication pain.

At baseline, subjects were able to walk 622±273 s on a specially designed ramp protocol treadmill test. Ankle brachial indices were diminished in both groups before and after exercise (non-PS indices =0.64±0.21 pre-exercise, 0.33±0.23 post-exercise; PS indices =0.67±0=20 pre-exercise, 0.46±0.19 post-exercise).

FUTURE PLANS—Our principles of interventional prevention and vascular rehabilitation may be applied nationally to create VA special clinics dedicated to enhancement of health via the proposed Polestriding exercise program. The reduction in the need for expensive, and labor intensive hospitalizations would also be cost-effective.

[191] COMPARISON OF LOWER-LIMB ARTERY SIZE IN MEN AND WOMEN WITH AND WITHOUT PERIPHERAL VASCULAR DISEASE: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #A2086-PA)*

PURPOSE—There is controversy regarding difference in artery size and treatment outcomes of women versus men. The objective of this study is to determine whether there is a difference in lower extremity artery size between men and women; whether lower extremity artery size is related to body surface; and whether lower extremity artery size is predictive of degree of vascular disease and bypass outcome.

METHODOLOGY—Height, weight, and body frame will be noted and intragroup match attempt will be done in order to minimize intragroup variables. Vascular status will first be assessed by segmental Doppler pressure profile and Doppler arterial blood flow waveforms. If noninvasive vascular studies are within normal range, the volunteer will then proceed to the second phase of the study which is having the peripheral artery size measured and blood flow velocity readings using Duplex scan imaging with spectra analysis. The common femoral, superficial femoral, profunda, popliteal, and posterior tibial arteries will be evaluated. When indicated, residual lumen will also be measured (% stenosis). Testing will be performed by a single Registered Vascular Technologist using the same Duplex imager, in order to eliminate technique and/or technical variables. Vessels will be imaged in both transverse and longitude planes. Duplex imaging examinations will allow for remeasurement by an independent observer.

This is a prospective, transverse and comparative study. Twenty volunteer controls (10 male and 10 female) with comparable height and weight will have diameter measurements of the arteries of the lower extremity (common, femoral, superficial femoral, profunda, popliteal, and posterior tibial arteries using Duplex scanning techniques. Correlation will be made with height and weight. Fifty persons (25 male and 25 female) with arterial insufficiency of the lower limbs will have measurements of artery size following the same protocol as the controls. The results be evaluated with t-paired tests and analysis of variance.

PROGRESS—The epidemiological knowledge of the measurement of artery size and its correlation with sex, height, and weight will help identify, in a more systemic and scientific manner, the possible risk factors. It will reveal if there is a significant difference in the size of the arteries of the lower extremity in healthy and diseased women by having an objective comparative with men. Blood flow velocities obtained will delineate normal velocities and velocities in varying degrees of disease.

To date, five females and one male have had screening for group designation in this study. The females qualified as controls (no peripheral vascular disease). Body surface areas were calculated in all volunteers and a match with opposite gender volunteers will be done. The volunteers with peripheral vascular disease had Duplex imaging and artery sizing and this information is being analyzed. The five females are scheduled for imaging shortly.

X. Orthopedics

A. General

[192] IMPROVED BONE CEMENT FATIGUE RESISTANCE VIA CONTROLLED STRENGTH INTERFACES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A796-RA)*

PURPOSE—The problem to be addressed in this study is to find a way to modify commercial bone cement to increase its fatigue resistance, especially its resistance to low stress, high-cycle fatigue without impairing its intraoperative handling characteristics.

METHODOLOGY—The basic methodology of the study consists of adding thin fibers to polymethyl methacrylate- (PMMA) based bone cement to improve its resistance to fatigue crack growth and thus increase its fatigue life. The fibers impede crack growth because the interface between the fiber and the cement matrix ruptures or debonds as the propagating crack approaches it. This serves to blunt the crack locally and also absorbs some of the energy of propagation that is the driving force for crack growth. If sufficient interfaces are present, the blunting and energy absorbing interactions can slow the overall rate of crack growth and increase the observed fatigue life of the cement. Optimization of this process depends on creating interfaces with moderate strength. The experimental approach is to modify the surfaces of the fibers before adding them to the bone cement by exposing them to low-pressure, low-temperature ionized gasses, (i.e., plasmas). This renders the surfaces reactive. When the cement-fiber composite cures, some degree of bonding occurs at these reactive surfaces producing an interface with the desired strength. The effectiveness of these interfaces in impeding crack growth is evaluated by measuring the strength of the composite in the presence of cracks (fracture toughness testing) and by measuring the actual fatigue life.

A secondary, but very important, concern is that the fiber additions can increase the viscosity of bone cement during mixing. This can interfere with proper mixing and hinder intrusion of the cement into the bone during surgery. To circumvent these effects, the size, composition, and loading of the fibers must be manipulated.

PROGRESS—During the second year of this study techniques and procedures were developed. Long (5 m) tows of polyethylene terephthalate (PET) fibers were procured and methods of handling, cleaning, chopping (to 1 mm length), and incorporation into bone cement were developed. These short fibers have supplanted the longer, 6 mm, fibers used during most of the first year of this study. Fibers are used in the ''as cleaned condition'' (controls) or are surface-treated by exposure to plasmas of oxygen, air, or argon before being added to the cement. Both fracture toughness and fatigue tests are in progress using molded (not machined) specimens. Attempts are also underway to assess the interface strength by the Iosipescu shear test and the short beam bend test. Electron spin resonance is being used to study the chemistry of the free radical (peroxide) accelerator reaction at the surface of the treated fibers. The conventional toluidene accelerator and a novel alternative accelerator, 4 methyamino phenethyl alcohol, are being evaluated.

RESULTS—A great many difficulties were encountered in preparing and testing composite specimens throughout the first 2 yrs of the study. These problems have been largely overcome, and testing is well underway. It has been demonstrated that reducing the length of the PET fibers to at least 0.5 mm improves the mixing and handling of composite bone cement without impairing its fracture toughness. It was also shown that machining (instead of molding) the notch in composite fracture toughness specimens leads to subsurface crazing around the embedded fibers. This, in turn, lowers the stress required for fatigue precracking.

Early fatigue results indicate that the endurance limit (at 1×10^6 cycles) of neat bone cement is 11.5 MPa. This is approximately 50 percent higher than the value that can be inferred from most of the prior work reported in the literature. This improvement is attributed to the greater care used in preparing and aligning the specimens in the present study.

FUTURE PLANS—The principal endeavor during the third year of the study will be the determination of the fatigue lives and endurance limits of fiber/bone cement composites following different surface treatments.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Machined vs molded notches in composite PMMA bone cement fracture toughness specimens. Friis EA, Kumar B, Cooke FW, Graber CD. Transactions of the 23rd Annual Society for Biomaterials; 1997 Apr 30-May 4, New Orleans, LA. vol. 20, p. 268.

The effect of treated PET fiber additions on the fracture toughness of composite bone cement. Friis EA, Kumar B, Cooke FW, Yasuda HK. Transactions of the Fifth World Biomaterials Congress; 1996 May 29-Jun 2, Toronto, ON. vol. 2, p. 348.

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Fracture toughness of surface treated carbon fiber reinforced composite bone cement. Friis EA, Kumar B, Cooke FW, Yasuda HK. Transactions of the Fifth World Biomaterials Congress; 1996 May 29-Jun 2, Toronto, ON. vol. 1, p. 913.

Modeling crack extension in chopped fiber composites. Friis EA, Hahn DL, Cooke FW, Hooper SJ. ASTM STP 1285: Composites Materials: Fatigue and Fracture; 1997;(6):364–78.

[193] DISUSE-INDUCED ARTICULAR CARTILAGE ATROPHY, OVER-EXERCISE, AND ARTHRITIS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A739-2RA)*

PURPOSE—We seek to measure biomechanical parameters in surface, middle, and deep layers of articular cartilage in disuse atrophy using a canine knee model caused by rigid immobilization for 6 wks, as well as disuse followed by 3 wks of conservative versus aggressive remobilization. We seek also to determine in the same animal preparation and articular cartilage layers metalloproteinase activity levels and cellular calcium fluxes with special reference to correlative changes. Critical changes in calcium flux, biomechanical properties, and elevation of endogenous proteases will be related to Dr. Setton's theory on loss of protective prestresses in disuse cartilage.

METHODOLOGY—We will determine the activities of the matrix metalloproteinases and TIMP in the articular cartilage of all joints at three zones through the cartilage layer to establish a baseline and to test for direct production of proteolytic agents following disuse or disuse with aggressive or conservative remobilization. We will then determine the site-specific material properties of articular cartilage at three zones in the articular cartilage layer in compression and swelling experiments. Measurements of the compressive modulus (Ha), Poisson's ratio (v), and Young's modulus (E) will be used to test for effects of periods of joint disuse, and disuse with aggressive or conservative remobilization, on the mechanics of the cartilage extracellular matrix. Fluorescent confocal scanning laser microscopy will be used to measure the transient changes in $Ca2^+$ in chondrocytes *in situ*— at three zones in the cartilage layer during compression of cartilage explants. This protocol will be repeated for all experimental cartilage to establish normal, site-specific mechanochemical interactions and to test whether these interactions are disrupted following periods of disuse or conservative or aggressive remobilization, and to test correlations with levels of metalloproteinases and proteoglycan content. A biphasic finite element model will be used with site-specific material parameters measured for articular cartilage to calculate the relevant mechanical parameters (e.g., fluid-flow, stress, strain, fluid pressure) at the cell-matrix interace for chondrocytes in the extracellular matrix. In this manner, we will use our site-matched data for mechanically induced $Ca2^+$ signaling *in situ* and predictions for mechanical signals to establish a baseline mechanochemical coupling, and investigate the hypotheses that the mechanochemical interactions change in surface zone cartilage during periods of joint immobilization to turn on proteolysis.

PROGRESS—Intense work on measuring disuse in comparison with normal femoral condylar cartilage, tangential versus radial zone cartilage, shows reduced cell size between zones. Chondrone cell volume compression modulus, relaxation time, trypan blue exclusion, and microbiomechanic investigations are all underway.

RECENT PUBLICATIONS FROM THIS RESEARCH

Mechanical behavior and biochemical composition of canine knee cartilage following periods of joint disuse and disuse with remobilization. Howell DS. Osteoarthr Cartil 1997;5:1–16.

[194] IMMUNOLOGICAL RESPONSES TO IMPLANT BIOMATERIALS FOLLOWING ARTHROPLASTY

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PURPOSE—Aseptic loosening, the loss of support by the surrounding bony architecture due to osteolysis, is the single most common complication of total joint replacement. Until recently, aseptic loosening has been theorized to be the result of surgical technique and prosthetic design. However, recent findings have focused attention upon the biological responses to plastics and metals in the pathogenesis of prosthetic loosening. The objective of this study is to identify the key components of the biological responses to implanted biomaterials by examining the hypothesis that implanted biomaterials elicit an inflammatory cellular immune reaction that may lead to osteolysis with eventual failure of the prosthesis.

METHODOLOGY—Immunological and molecular techniques are being used to assess both the serological and cellular responses directed against biomaterials in persons with aseptic loosening. We are examining failed prosthetic implants for the presence of antibodies bound to the implant surface, or reactive with proteins bound to the implant. Electrophoresis (SDS-PAGE) is performed to determine the number and molecular weight of bound proteins extracted from the surface of failed polyethylene implants recovered during surgical revision procedures. Specific proteins in the extracts are analyzed by immunoblot and Western blot techniques. Celluar responses to biomaterials are measured in peripheral blood mononuclear cells (PBMC) from subjects with painful or loosened total joint prostheses, and from those pre-operatively qualified for total joint replacement. Cells are cultured *in vitro* with polymethylmethacrylate (PMMA) cement, ultra high molecular weight polyethylene (UHMWPE), cobalt-chrome alloy (Co-Cr), and titanium (Ti) particles, and the prolifeative and cytokine responses to each biomaterial are calculated. We are also developing an animal model of the response to wear debris, and using gene therapy as a novel approach to combat the inflammatory reaction in tissue surrounding the prosthesis.

PROGRESS—Extracts from 52 failed prostheses have been evaluated for bound proteins. Cellular responses to biomaterials in particulate form have been evaluated in 185 subjects. Changes in the responses 1 yr after implantation have been assessed in 32 subjects. Image analysis techniques and RT-PCR assays have been established to evaluate the air pouch model. Gene therapy using the IRAP contrakine gene has been preliminarly evaluated in the model.

RESULTS—Type I collagen was detected on the majority of failed prostheses (45/52), while aggrecan proteoglycans were rare (8/52). Bound immunoglobulin was detected frequently (41/52), and antibodies reactive against the UHMWPE bound proteins were detected in autologous sera from 26/38 implant recipients. Most autoantibodies were directed against high molecular weight proteins. There was an association between the presence of antibodies to implant-bound proteins and the occurrence of serum antibodies to type I collagen. Cellular activity in the subjects revealed that the response to PMMA and to CoCr was significantly higher in the revision surgery group compared with the primary surgery group. In vitro IL-1 production in response to stimulation with PMMA reflected the proliferation results closely, and levels of IL-6 were observed in cells stimulated with Ti-6Al-4V particles. High responses to PMMA were observed in subjects undergoing revision surgery due to loosened or painful prostheses, while responses to PMMA in those undergoing revision surgery due to mechanical failure or infection were not elevated. The murine air pouch response to prosthesis wear debris proved to be an accurate model of the inflammation in periprosthetic tissue. Gene therapy techniques resulted in the production of the contrakine IRAP within the pseudosynovial tissue, with a concommitant improvement in several parameters of the inflammatory reaction in the air pouch.

RECENT PUBLICATIONS FROM THIS RESEARCH

Cellular immune responses to orthopaedic implant material following cemented total joint replacement. Wooley PH, Petersen S, Song S, Nasser S. J Orthop Res. In press.

The immune response to implant materials in humans. Wooley PH, Nasser S, Fitzgerald RH Jr. Clin Orthop Rel Res 1996;263: 63-70.

A model of cellular responses in aseptic loosening: UHMWPE and PMMA particles provoke different responses in the murine air pouch. Wooley PH, Morren R, Andary J, et al. Orthop Trans 1996;21:500.

Synergistic inflammatory responses to metallic and polymeric particles in the murine air pouch model of aseptic loosening. Wooley PH, Mayton L, Sud S, Nasser S. Arthritis Rheum 1996;39:s175.

Cellular proliferation and cytokine responses to polymethylmethacrylate (PMMA) following joint replacement. Chadha HS, Wooley PH, Fitzgerald RH Jr. Inflam Res 1995;44:145–51.

[195] BIOCHEMICAL ANALYSIS OF SYNOVIAL ACTIVATION IN JOINT DYSFUNCTION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A52-8RA)*

PURPOSE—Prior research in this laboratory has generated the hypothesis that interleukin-1 (IL-1) is an important autocrine mediator of the activation of mesenchymal cells by wear particles, and of the osteolysis that follows activation of these cells. These mechanisms are thought to drive the process of aseptic loosening of prosthetic joints. It follows that inhibition of IL-1 should protect against the osseous changes that produce aseptic loosening. The interleukin-1 receptor antagonist (IL-1 Ra) is a naturally occurring inhibitor of IL-1. We suggest that IL-1 Ra should be a useful agent with which to prevent aseptic loosening, and that its delivery by gene transfer is the most expeditious way to realize its potential in this regard.

METHODOLOGY—In the *in vitro* studies, a retrovirus (MFG-IRAP) is used to transfer a gene encoding the human IL-1 Ra protein to synovial fibroblasts. These cells then secrete constitutively large amounts of human IL-1 Ra into their culture medium. The cells are then challenged with a number of activating stimuli including phorbol myristate acetate (PMA), 1L-1 and particles, generated from prosthetic joints. The degree to which the IL-1 Ra gene prevents the synthesis of IL-1, matrix metalloproteinases (MMPs) and prostaglandin E_2 (PGE_2), is then noted.

The recombinant retrovirus is produced by cloning a hTL-1 Ra cDNA into the backbone of the MFG retrovirus. This is used to transduce the cell cultures. Expression of IL-1 Ra is assessed by ELISA. PMA, IL-1, or particles are then added to the cultures, and the expression of IL-1, MMPs, and PGE_2 measured by standard.

PROGRESS—The MFO-IRAP vector efficiently transduces the IL-1 Ra gene into primary cultures of rabbit and human synovial fibroblasts, as well as chondrocytes and bone marrow hematopoietic stem cells. Transduction of fibroblasts was found to be greatly enhanced by centrifuging for 2 hr during the period of viral infection. Transduction of the rabbit synovlal cell line HlG-82 generated a stable line (HIG-IRAP) that constitutively produces large amounts of IL-1Ra (>100 ng IL-1Ra/10^6 cells/day) and provides a useful experimental tool. Expression of IL-1 Ra not only inhibited induction of mediators by cells exposed to wear particles but, surprisingly, also protected them from the cytotoxic effects of high doses of these particles. This suggests that the latter process is subject to biological control and may be apoptotic in nature.

IMPLICATIONS—Aseptic loosening is the major reason that joint replacements fail. This project investigates one way to prevent it.

[196] AN IN-VIVO MODEL FOR CARTILAGE REGENERATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A799-3RA)*

PURPOSE—The reason for this study is to evaluate the potential for development and maturation of cartilage or cartilage-like tissue on an articular surface *in-vivo*, with the study joint allowed full mobility.

METHODOLOGY—The model for this project is the articulating surface of the dog patella, selected for the early phase of our investigations because the mechanical stresses upon the dog patellae are very large, much like the human counterpart. Also, this model provides sufficient material for the extensive histologic, biomechanical, and chemical studies required to evaluate the tissue which grows on the subchondral bone surface after all normal cartilage has been removed. The uncovered subchondral bone surface on the experimental patella is prevented from coming into contact with the femur by inserting high density, polyethylene spacers. Thus, a shielded space is created in the moving joint that allows new tissue to grow in an otherwise normal joint where mechanical stress will not damage the new tissue.

PROGRESS—The project is entering phase three of a five-step study. Phase one answered the question, will new tissue grow on a subchondral bone surface in a shielded environment. That question has been answered affirmatively with histologic, biomechanical, and biochemical evidence of a neo-cartilage tissue growing to completely fill the shielded area on the subchondral bone surface. Phase two utilized the refined model to produce useful study material. The object of this phase was to learn at what time point the new tissue would reach maximum maturation in this stress-shielded environment.

RESULTS—We have determined that 12 wks after the experimental operation, the new tissue reaches a peak of maturation during stress shielding and begins to fibrillate at its surface, and there is increasing evidence of injury to the joint caused by the shielding devices, the polyethylene spacers. With this observation completed we have begun to remove the shielding devices, so that the new tissue can be exposed to the contralateral joint surface covered by normal hyaline cartilage. This third phase will include the same histologic, biomechanical, and biochemical assessment of the new tissue's ability to survive and function after having been subjected to compression and motion stress.

FUTURE PLANS—The next phase of this study will be devoted to an evaluation of the response of the new tissue at three time points (4, 8, and 12 wks) after the shielding devices have been removed. Of course, we hope the new tissue will continue to change into a mature form of fibro-cartilage and will survive to act like normal hyaline cartilage on the joint surface. If it does not, we plan to try to modify the new tissue to act more like normal hyaline cartilage by chemical means with growth factors, and the like.

[197] EFFECT OF RESTORING POSTERIOR TIBIAL TENDON FUNCTION IN AN ACQUIRED FLATFOOT MODEL

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Sponsor: *None listed*

PURPOSE—This study examines the effect of restoring posterior tibial tendon (PTT) function in an acquired flatfoot model. Rupture of the PTT is associated with progressive or acquired flatfoot deformity. Treatments include various fusions, lateral column lengthening, ligament reconstruction, and tendon transfer. This study uses an acquired flatfoot model to test the hypothesis that restoring PTT function (simulating repair) will significantly affect the kinematic orientation of the hindfoot complex in heel strike, stance, and heel off.

METHODOLOGY—Eight human cadaver lower leg and foot specimens were obtained. Gross inspection and radiographic screening were performed to rule out pre-existing pathology. The soft tissue was stripped from around the tibial shaft of each specimen exposing the remaining tendons to the hindfoot level. Carbon fiber pins were placed into the calcaneus, talus, navicular, and cuboid and positioned so as not to interfere with the joint motions. An acrylic rod was inserted into the intramedullary canal and crosslocked to permit axial compressive loading of the foot.

To create an acquired flatfoot model, the spring ligament was divided and the specimen subjected to cyclical loading on an MTS hydraulic load frame. Peak loads of 2.5 times body weight were applied for 5000 cycles at 1 Hz. A radiolucent load frame was used to apply a static 75N compressive load on the foot while taking lateral and A-P radiographs of each specimen both before and after flattening. These radiographs were used to document the degree of deformity for each foot.

Simulated axial compressive and tendon loads were applied to each specimen using a custom acrylic foot loading frame that allowed for three different loading positions for each foot: heel strike, stance, and heel off. These positions were achieved by applying different combinations of axial compressive and tendon loads in appropriate ratios while placing each foot on an inclined surface. The degree of incline selected for each position included 6° of plantar flexion for heel strike, 7° of dorsiflexion for stance, and 10° of dorsiflexion for heel off. Tendon loads were calculated from physiological cross-sectional areas, reported peak forces, and normalized EMG values.

Each specimen was mounted within the foot loading frame, and nylon cables with tendon clamps were used to connect the tendons of the foot to regulated pneumatic cylinders. A central pneumatic cylinder was used to compressively load the foot via the tibial intramedullary rod. 3-D motion sensors were attached to each of the four carbon fiber pins. These electromagnetic sensors were used to track the 3-D motions of the hindfoot bones. The transmitter was mounted onto the loading frame so that its Z-axis aligned with the long axis of the tibial shaft, the X-axis was directed along the medullary canal of the second metatarsal, and the Y-axis was perpendicular to these two axes (approximately medial-lateral). This unloaded position of the foot was the initial position. 3-D motion (bone orientation) data was collected for each of three conditions: initial position, all tendons loaded except the PTT (All−PTT), and all tendons loaded including the PTT (All+PTT). This protocol was repeated for each of three different foot positions (heel strike, stance, and heel off).

For each test, all of the motion data was transformed such that both the All−PTT and All+PTT data were reported relative to the initial position. A nonparametric, Wilcoxon Signed Rank paired analysis was then used to statistically compare the angular orientation of the four bones for both conditions. This analysis was performed for all three loading positions including heel strike, stance, and heel off.

RESULTS—Small but statistically significant changes in the angular orientation of the four-bone complex were observed when the PTT tendon was loaded (All+PTT) as compared to unloaded (All−PTT) for all three foot positions. These differences were typically less than 1 degree, particularly during heel strike and stance simulation. The greatest changes in angular orientation resulting from loading the PTT were seen during heel off. This was not surprising since the PTT is most actively recruited during this phase of the gait cycle. Talar (3.6°±1.2, $p=0.011$) and calcaneal (2.3°±0.5, $p=0.011$) internal rotation together with talar plantar flexion (1.4°±0.9, $p=0.011$) was observed when the PTT was loaded. Eversion of the navicular (3.9°±2.0, $p=0.011$), cuboid (2.4°±0.9, $p=0.011$), and calcaneus (2.0°±0.8, $p=0.011$) was also observed at heel off.

CONCLUSIONS—Restoring function to the PTT in an acquired flatfoot model had little effect on the kinematic orientation of the hindfoot complex. Although there were statistically significant differences between the All−PTT and All+PTT conditions, these differences were typically less than a few degrees. These results suggest that restoring PTT tendon function alone may not fully correct a radiographically documented flatfoot deformity.

[198] PRECONDITIONING AS A TECHNIQUE TO MINIMIZE TOURNIQUET-INDUCED MUSCLE INJURY

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PURPOSE—Tourniquets are frequently applied in extremity surgery to minimize blood loss and to improve surgical field visualization. Unfortunately, a degree of risk is associated with the ischemic period experienced by the limb during tourniquet application. The pupose of this research is to develop a methodology to minimize the risks associated with the use of tourniquets during extremity surgery.

METHODOLOGY—Preconditioning is a technique which consists of a brief period of ischemia (5–10 min), followed by re-perfusion for an equal amount of time before the prolonged ischemic episode. Our research regarding this technique includes incremental steps that address immediate effects in an animal model through clinical application during arthroscopic surgery.

PROGRESS—The intraoperative effects of muscle preconditioning have been investigated in a cat model, where the medial gastrocnemius muscle strength is tested during and immediately after tourniquet application. Our results show that preconditioned muscles maintain a significantly higher ($p<0.005$) ability to contract 1 hr after tourniquet application.

A prospective, randomized study is being performed to assess the effect of preconditioning on the leg muscles of arthroscopy patients.

RECENT PUBLICATIONS FROM THIS RESEARCH

Myoelectric and mechanical changes elicited by ischemic preconditioning in the feline hindlimb. Phillips DJ, Petrie SG, Zhou B-H, Guanche CA, Baratta RV. J Electromyogr Kinesiol. In press.

[199] A SURVEY OF PARENTS OF CHILDREN WHO USE ORTHOSES AND PROSTHESES

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Sponsor: *National Institute of Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 22202*

PURPOSE—This study focuses on three specific issues: 1) to identify parents' perceptions of minority community views of health, illness, the importance of motor skills, and the implications of orthopedic disabilities for children; 2) to identify parents' personal views of health, illness, motor skills, and orthopedic disabilities with reference to children; 3) to identify the specific parent actions taken to secure child services with respect to orthotic and prosthetic devices.

METHODOLOGY—The study involves parents of children who have orthopedic impairments and who range in age from the preschool years through late adolescence. Upon signing a consent form, parents are interviewed in their homes and at their convenience. Data analyses will involve reliability checks of the instrument, descriptive statistics for subgroups (e.g., ethnic group membership, age of child), relevant dimensions, and if numbers allow, multiple regression analyses to identify the variables that contribute to parents accessing the system for assistive devices for their children.

PROGRESS—Information packets have been designed to acquaint parents and others with the goals of this study. In addition to parents, target recipients include community leaders, directors of regional centers, and others who might directly or indirectly be involved with families appropriate for this study. Each packet contains a letter that briefly describes the project and requests parent participation, a fact sheet that provides details about the project, and a postage-paid return postcard. Packets are available in English and Spanish.

Resource guides have been designed to provide key access information to parents about local service organizations, support groups, and legal resources that cater to the needs of individuals with handicapping conditions. In addition, the guides supply practical information about the prevention of child abuse, consumer resources, disaster preparedness, housing assistance and tenants' rights, community resources geared to combat harmful gang activities, and neighborhood programs focused on literacy and English as a second language. The guides will be provided to parents as a benefit for participating in the study.

Many hundreds of information packets have been distributed to interested community agencies, who in turn, forwarded the packets to parents who might participate in the study. To date, more than 70 parents have indicated an interest. Telephone contacts are made after receipt of postcards. A preliminary screening identifies children who meet subject criteria (e.g., an orthopedic problem, normal intellectual functioning or mild developmental/cognitive delay, chronological ages between 2 and 17 years). Approximately 50 percent of responding parents have children who do not meet subject criteria. Most frequently, the children have major neuromuscular disorders and/or severe cognitive impairments.

Thirty interviews have been completed with parents who represent diverse cultural and ethnic backgrounds; their children have various kinds of orthopedic conditions. Although the interviews are lengthy, parental commitment to the interview is impressive. Apparently parents welcome the opportunity to talk about their child and their parenting experiences. Recruitment continues in order to meet the study target goal of a minimum of 100 participants.

The interview data base is being established. Code books and variable lists are being developed, and to date, information on 40 variables has been entered.

B. Hip Implants

[200] FATIGUE STRENGTH OF COMPOSITE FEMORAL COMPONENTS FOR HIP ARTHROPLASTY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A670-3RA).*

PURPOSE—The purpose of this research is to investigate how the design of composite femoral components influence fatigue behavior, and how components should be mechanically tested *in vitro* to closely simulate *in vivo* stress states. The goal of this research program is to develop the necessary technology base to enable low stiffness/high strength composite femoral components to be confidently designed and tested for clinical use with the potential for reducing stress-shielding-induced proximal bone resorption following hip arthroplasty. The reduction of bone resorption following arthroplasty should promote longer femoral component life and significantly reduce complications in revision surgery.

METHODOLOGY—In Phase 1 of our research, a detailed anatomic 3-D computer model of the proximal femur with an *in situ* composite femoral component is being developed to investigate relationships between composite femoral component design and fatigue performance under simulated *in vivo* loading conditions. In Phase 2, similar numerical modeling and analysis techniques will be applied to determine the proper experimental parameters to be used in Phase 3 for actual fatigue testing of composite stems for model verification. Test parameters and fixture design will be studied to provide component stress states during fatigue testing that closely match those expected *in vivo.* Once the proper experimental parameters have been established, composite femoral components will be fabricated and fatigue tested in Phase 3. Results are expected to provide a detailed understanding of how composite structural design will influence fatigue behavior under simulated *in vivo* loading conditions. This knowledge is essential to enable composite femoral component technology to be developed for successful clinical application toward the goal of improving hip joint replacements.

PROGRESS—Phases 1 and 2 have been completed, yielding composite femoral components to be closely simulated in Phase 3. Under Phase 3, a new thick composite plate fabrication hot-press has been prepared for operation and utilized for the fabrication of trial composite laminates. Thick composite plate molds have also been designed and are currently being produced. The molds will be used for the fabrication of the thick composite plates that will be machined into the composite femoral components for fatigue testing.

PRELIMINARY RESULTS—Experimental verification testing demonstrates that the developed computer models accurately predict the mechanical behavior of the femur. Preliminary results of the computer models have been obtained to study the femoral model response under the three load-bearing phases of gait (heel-strike, mid-stance, and toe-off) and stair-climbing. Additionally, the preliminary results from fabricated AS4/APC2 composite plates have shown the new lamination press to produce quality laminates as is necessary for the fabrication of the composite femoral components that will be tested.

FUTURE PLANS—Now that the femoral computer model is completed and verified, it will be utilized during the upcoming year for fatigue modeling studies to evaluate relationships between composite femoral component design and fatigue performance. Composite femoral components will then be fabricated according to the computer model design results. The design and fabrication of the experimental test apparatus will also be completed within the upcoming year and be utilized to experimentally study and document fatigue behavior of the new femoral component designs.

[201] THE EXAMINATION OF EXPLANTED, UNCEMENTED ORTHOPAEDIC PROSTHESES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A473-3DA)*

PURPOSE—The overall objective of this study is to assess the long-term feasibility of porous coating as a mechanism for fixing orthopaedic prostheses to bone. Additionally, the role of design and material in the performance of these prostheses is being determined through this analysis.

METHODOLOGY—This examination of clinically retrieved, porous-coated hip and knee prostheses will assess the importance of such variables as material composition, design, location of porous coating, pore size, and surface roughness on the resulting interface between the prosthesis and bone. The study will address the issues of stress shielding, ion release, and wear debris formation, and will clarify, where possible, causal relationships with prosthesis parameters.

Retrieved prostheses are fixed in formalin and examined macroscopically and graded for wear, corrosion, fretting, and tissue adherence. The metal components are mapped for both soft and hard tissue apposition prior to being embedded, cut into standard histological sections, and stained. Serial sections permit the assessment of bone resorption or of stress shielding for prostheses that are retrieved intact as post-mortem specimens. The polyethylene bearing surfaces are graded for damage and defects and then sectioned on the microtome to determine the degree of polyethylene consolidation.

PROGRESS—We presented several recent studies at the American Academy of Orthopaedic Surgeons meeting in San Francisco in February 1997. These studies highlight the results of our current investigations and will be published.

The Impact of Sterilization Method on Clinical Damage of UHMW Polyethylene Knee Components

Seventy-six retrieved, unicompartmental polyethylene bearings were rated macroscopically for clinical wear. They represent 7 different manufacturers and 13 different designs. A Jung microtome was used to shave 200 micron thin films from the cross section of a variety of the polyethylene bearings. The thin sections were examined under reflected light at 10–60× for the presence of a subsurface white band, shown to be an indicator of gamma ray-induced oxidation. Sterilization method was determined from manufacturer information and by oxidation spectra from Fourier Transform Infrared Spectroscopy (FTIR).

RESULTS—Fifty-three of the knees were gamma irradiated. Their average *in vivo* duration was 65 mo. Cracking and/or delamination were present in 57 percent (30/53). Complete wear-through of the polyethylene occurred in 21 percent (11/53), and the white subsurface band was apparent in 84 percent (16/19).

The remaining 23 knees consisted of 3 designs from the same manufacturer; all were implanted within the time period that this company is known to have been using EtO for sterilization. Their average duration was 155 mo. Cracking and/or delamination was absent. Both complete wear-through of the polyethylene and the white subsurface band were absent in all cases.

CONCLUSION—Retrieved polyethylene knee components gamma irradiated in air are observed to have a high incidence of cracking and delamination (>50 percent), leading at times to complete wear-through of the bearing. Knee components sterilized with EtO have little evidence of fatigue wear even after *in vivo* durations of >15 yrs.

Shelf Versus In Vivo Oxidation of Polyethylene Orthopedic Inserts

Retrieved ultra high molecular weight polyethylene (UHMWPE) inserts were sectioned by microtome and analyzed microscopically for the presence of a subsurface white band, which signifies oxidative degradation of the material. FTIR spectroscopy was used to determine the oxidation products as a function of depth into the inserts. Uniaxial tensile testing of thin sections measured the UTS and elongation of the material. Hexane extraction of retrieved insert thin sections was used to differentiate oxidation products from *in vivo* absorbed species. Never-implanted UHMWPE inserts were analyzed in a manner similar to that for the retrieved inserts. Insert sterilization dates were obtained from the manufacturers.

RESULTS—More than 25 retrieved and 20 never-implanted UHMWPE inserts gamma sterilized in air have been evaluated. Oxidation in retrieved inserts is more complex than in shelf-aged inserts. Retrievals can exhibit surface oxidation, either alone or in addition to a subsurface oxidation maximum. Surface oxidation, a result of *in vivo* duration, follows a diffusion gradient from the surface of the component. It is a result of absorbed species (esters) that are extractable with hexane. All components show a trend of increasing oxidation and decreasing mechanical properties with increasing time on the shelf prior to implantation. Large differences in clinical wear (particularly delamination and cracking) also appear to relate to pre-implant shelf time.

CONCLUSION—Retrieved inserts exhibit a large variation in oxidation and mechanical integrity. Inserts of the same design and material show extremes of performance *in vivo*. While gamma sterilization in air is detrimental to polyethylene in general, the process does not always lead to degradation *in vivo*. This study differentiates the very near surface oxidation (absorbed species) from *in vivo* degradative oxidation reactions with the polyethylene. Variations in polyethylene insert history (pre-implant shelf time vs. *in vivo* duration) are found to be largely responsible for mechanical property changes that lead to variations of performance *in vivo*.

PROJECT SUMMARY—We have evaluated more than 500 retrieved components this year bringing our total above 5,000. We continue to gain insight into the factors which influence implant performance including: design, wear in service as well as the polyethylene material variations. Our recent publications have focused primarily on the effect of sterilization on the polymer bearings of the joint replacements.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[202] IMPLANT RETRIEVAL RESEARCH, RESULTS AND CONCLUSIONS, 1988–98: A SPECIAL REPORT

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Projects #A473-1DA; #A473-2DA; #A473-3DA; #A473-4DA: 1988–98)*

PURPOSE—Arthritis of the hip and knee is a crippling disease for which joint replacement represents a compelling option to relieve pain and increase mobility. In fiscal year 1986, replacements for 3,068 hips and 362 total knees were performed in the VA system alone. Of these, a significant number would fail, due to a breakdown of the interface between the prosthesis and the host bone of the patient. According to representatives of the three largest manufacturers, nearly half of their orthopaedic implant sales in 1986 were porous-coated designs. While this represented a significant use of these prostheses by orthopaedic surgeons, there was no central resource available for evaluation of their performance, and virtually no clinical information in the literature. This need prompted the VA to establish a center to conduct follow-up studies of the failed devices, to provide direct feedback to the implanting surgeons, and to improve the overall medical care of those undergoing joint replacement.

For the past decade, The Center for the Examination of Retrieved Orthopaedic Prostheses has been the largest program of its type in the country, receiving approximately 600 components per year from more than 700 participating surgeons: in the first 8 years of this VA-funded program, we evaluated more than 5,000 orthopaedic prostheses. This research has led to a number of unanticipated and important findings about the performance of artificial hips and knees.

At the Center's inception in 1988, the predominant joint replacement technologies were evenly divided between cemented and uncemented/porous coated implants. Fixation of the implants was the greatest problem in joint replacement, and our original objective was to determine whether porous coating resulted in improved long-term fixation of orthopaedic prostheses to bone. Our analysis provided a way of identifying problems with implants and allowed evaluation of the performance of competing technologies, including porous coated versus non-porous coated implants; bead/pore size of the porous coating; and titanium versus cobalt.

Since then, concerns regarding the integrity of porous coatings, the longevity of hydroxyapatite surfaces, the potential for modular connections to fret and corrode, and most recently, the impact of gamma radiation sterilization on the performance of polyethylene (PE) bearing surfaces, have all arisen from the examination of retrieved prostheses, while joint replacements have increased to over 350,000 each year in the US. We have built a large database to track the influence of design, material, and fabrication techniques on clinical outcomes and expanded the scope of our research to include the overall design and performance of the artificial joints and the impact of PE quality and sterilization upon them.

METHODOLOGY—Upon arrival at the Center, retrieved implants are soaked in formalin for 48 hours, then air dried and examined macroscopically. The prostheses are evaluated for both soft and hard tissue ingrowth to the implant. The metal is rated for burnishing, scratching, abrasion, and fretting; the PE is rated for burnishing, scratching, abrasion, pitting, delamination, creep, and cracking. Both metal and PE are graded on a scale of 0 (absence of the phenomenon) to 3 (presence of severe amounts of the phenomenon).

Depending on the initial evaluation results and specific implant characteristics, further analysis may be required. To determine the extent of bone ingrowth, and amount of metal and PE debris, implants are embedded, sectioned and stained in preparation for histological evaluation. Modular components are evaluated for evidence and severity of corrosion. PE is measured for wear and tested for chemical and mechanical properties. All data are entered into the database mentioned above.

Overall Design and Performance of Hips

Prior to 1977, the only alternative to direct contact between the metal of the prosthesis and the bone of the patient was the bone cement polymethylmethacrylate (PMMA), inserted as a luting agent between the two and allowed to polymerize *in situ.* While this material increased comfort for the patient and provided the surgeon with better assurance of a good fit, it proved to have poor fatigue properties; a significant number of cemented prostheses failed at the cement/bone interface.

In 1977, an alternative was made available in the form of a porous metal coating applied first to femoral hip prostheses. Unlike cemented prostheses that require no biological response for fixation, porous coated devices require ingrowth by bone and fibrous tissue (osseointegration) to develop an interface maintained by the body and therefore not subject to this fatigue failure. Osseointegration is considered successful if bone tissue grows directly into the pores of the coating. Well-organized fibrous tissue-ingrowth can also provide satisfactory implant fixation in some cases. Our research has shown that the primary requirement for satisfactory ingrowth is initial rigid fixation with a tight press fit of porous coating against bleeding bone. In a recent study of 1,050 retrieved porous-coated, uncemented hip components with *in vivo* durations greater than 2 months (521 acetabular cups, 536 femoral stems), 218 of the cups (42 percent) and 275 of the 536 stems (51 percent) displayed some extent of bone ingrowth.

In revision hip prostheses, it can be difficult to obtain the required tight press fit of porous coating to bone because of the large, irregular proximal femoral canal and an irregular diaphyseal geometry. In these cases, fully porous-coated prostheses can afford the necessary contact of coating against living host bone. Also, proximally coated femoral hip prostheses, when used with femoral allografts, may place the porous coating against dead bone and, therefore, bone ingrowth cannot reasonably be expected. However, substantial fibrous ingrowth from an endosteal response can be expected, and may be sufficient to fix the prosthesis to the graft. In addition, the firm fixation of acetabular components in revision surgery can be more difficult than the fixation of femoral components. Acetabular components fixed with screws are not immune to micromotion, which can generate metal debris, as evidenced by blackening of the tissue in the region of the screw holes.

The early porous-coated prostheses had an average pore size of less than 50 µm. Early retrievals displayed fibrous tissue ingrowth but no ingrowth by bone. Animal experiments and evaluation of human physiology indicated that pore sizes of at least 100 µm would be required to permit bone and its attendant blood supply to grow into the prostheses. Subsequently, pore sizes were increased, and later retrievals had evidence of bone ingrowth. Today's prostheses have pore sizes ranging from 100 to >1,000 µm. Histologic evidence indicates that for most hip and knee components, pore size variation within this range is not critical to the performance of the prosthesis, and examples of dense bone ingrowth for most every type of component has been observed.

The surface roughness of the porous coating is, however, a function of the powder size and pore size of the coating. It is apparent that larger pore size prostheses have a smoother surface than small pore size prostheses. Therefore, prostheses which rely only on the frictional fit of the coating against reamed bone must take this into consideration. Prostheses with large pore size and relatively smooth surfaces may need screws, threads, or pegs to provide initial stabilization until ingrowth fixation is established.

Current interest in the use of coatings, particularly plasma-sprayed hydroxyapatite (HA) and tricalcium phosphate (TCP), on femoral and acetabular hip prostheses is based upon a large series of studies showing calcium phosphate ceramics to be osteoconductive in animals. There is a general consensus that calcium coatings on smooth-surfaced prostheses produce improved mechanical fixation for up to 12 weeks postoperatively. At longer periods, the results are mixed: some studies show increased bond strength, others show none.

The results of the use of HA coatings on porous-surfaced prostheses are somewhat more difficult to interpret. In our early animal studies, there was more bone ingrowth with HA coating, but the mechanical fixation strengths were similar at all time periods. Also, it was generally observed that the HA/bone bond interface was stronger than either the HA-implant interface or the HA coating itself. HA has been shown to be resorbable in animal experiments, and it appears that this is also the case in the clinical setting. How long the resorption takes is subject to a large number of variables, including the type of bioceramic applied, the degree of crystallization, the thickness of the coating, and its level of density and coherence.

It appeared to us that the weak link in some systems was the HA-implant bond. Examination of six retrieved HA-coated components demonstrated direct bone adherence to the HA. Areas not in contact with bone appear to absorb first. Rates of resorption were quite variable, with examples from some manufacturers demonstrating complete resorption after 6–9 months *in situ* and components from another manufacturer demonstrating considerable HA at 48 months. Histologically, the bone/HA bond appears to be quite as secure as bone ingrowth; removal of both systems requires removal of surrounding bone due to the strength of that bond. Although HA appears to be osteoconductive, it does not appear that HA can be considered the sole long-term mechanism for fixation of prostheses, due to its limited initial bond strength to the substrate and the ability of the host to resorb the material over time. Therefore a stable implant geometry and a textured titanium surface suitable for bone adherence may be critical for long-term fixation.

Material Composition

In the early 1980s, the desire for reduced femoral hip-stem stiffness lead to the increasing use of titanium alloys (Ti 6A1 4V, ASTM F-136-79) in place of the stiffer cobalt-chrome materials (HS 21, ASTM F-75). Although concerns were expressed for its use in cemented applications because of its flexibility and associated increased risk of failure of the cement mantel and the potential for metal ion release if the stem became loose, there has been little concern about its application for use in press-fit or biologic fixation applications. The fatigue characteristics of titanium alloy are excellent under cyclic loading, and it is a very workable metal, easily milled to tight tolerances.

Titanium has achieved acceptance over cobalt alloy for dental implants, due to the belief that the likelihood of osseous integration is greater; laboratory testing in animals and a study of porous plugs of both materials in humans has tended to support the merits of titanium. The trend toward the use of the more easily machinable titanium alloys presented the opportunity to compare the ingrowth frequencies of the two alloys in components of similar design, manufacturer, porous coating type, and pore size.

We examined 109 acetabular components for ingrowth, 46 composed of cobalt alloy, 63 of titanium alloy. All had durations *in vivo* >2 mo, and no severe wear of the metal or PE was evident. The average implant duration of the devices was 34 mo for the cobalt and 37 mo for the titanium. Eight of the 46 cobalt alloy cups (17 percent) and 36 of the 63 titanium devices (57 percent) presented bone ingrowth. With design variables minimized, the frequency of bone ingrowth into titanium alloy components was more than three times greater than those of cobalt, supporting the contention that porous coated acetabula composed of titanium are more likely to have successful biologic fixation than those of cobalt alloy. Femoral hip components do not present as close an opportunity for direct comparison as acetabular cups, and both titanium and cobalt alloy components are often observed to have become bone ingrown. Ingrowth of knee components appears to be directly related to quality of fixation, especially in the tibial component. Well-fixed titanium components were observed to demonstrate a greater frequency of ingrowth than cobalt alloy devices but direct comparisons have not been possible.

First-generation titanium-alloy femoral hip components with integral heads were seen to suffer scratching, burnishing, and loss of head sphericity to a greater degree than their cobalt-alloy counterparts. From the mid-1980s to date, it appeared that the solution of a cobalt-alloy head on a titanium stem was satisfactory for both press-fit and biologic ingrowth applications. The titanium alloy stem provided reduced stiffness, and the tougher cobalt-alloy femoral head provided improved wear resistance against the PE. This trend toward modular prostheses that permit variable neck lengths through separate heads and stems mated at the time of surgery, provided manufacturers the opportunity to combine dissimilar metals. Since then, modular hip prostheses have become the standard cementless design and account for a large percentage of the cemented hip market as well. This reflects a compelling interest within the surgical community in the technical advantages accorded by modular design. The 2-piece acetabular components with separate shells and bearings, and femoral stems with modular heads, have led more recently to designs with increasing numbers of components. Potential benefits of this increased modularity include intraoperative flexibility in implant geometry resulting in improved fit, optimization of materials, simplified revision surgery, and, with improved patient outcome, a long-term reduction in overall costs.

Although modular hip prostheses have become dominant over one-piece configurations, the use of these devices has not been without complications. Several researchers have reported the failure of modular and factory-assembled acetabular components through disassociation of the liner and shell. Reports of corrosion and fretting of modular femoral stems, and the contributory roles of these two phenomena in the generation of debris, also are common in the literature. Modularity requires a mechanical coupling of parts by the surgeon at the time of surgery; as a result, the attention to surgical cleanliness and the technique used to assemble the parts may influence the ultimate longevity of the component in service. In addition, the quality of the materials and the accuracy of the machining of the mating surfaces are likely to play a role in performance. Modular components inherently have more potential modes of failure than one-piece devices, and each modular connection is a potential site for fretting, corrosion, and disassociation.

One major concern arising during development of the cobalt-alloy head/titanium-alloy stem femoral hip components was their potential for multi-alloy crevice corrosion, deterioration occurring within crevices and other shielded areas of metal surfaces exposed to corrosives such as body fluids. Crevice corrosion may be differentiated from fretting corrosion in that the former requires no relative motion between surfaces, whereas the latter occurs from a combination of motion and corrosion. However, the amount of motion required to produce fretting is so small (on the order of microns) that it may be difficult if not impossible for a visual analysis to eliminate the potential for fretting as a contributor to corrosion of retrieved components. A crevice corrosion site must be wide enough to allow liquid to enter but narrow enough to create a stagnant zone: openings a few thousandths of an inch or less in width are sufficient.

The mechanism for crevice corrosion of both similar and dissimilar metals, involves the dissolution of the metal alloy into its respective ions and the reduction of oxygen to hydroxide ions (Oxidation $M[cd]M^{+}e$; Reduction $O_2+2H_20+4e[cd]4OH^{-}$). The oxygen within the crevice is depleted because of restricted convection. This tends to produce an excess of positive charge in the solution, balanced by the migration of negative chloride ions into the crevice. The fluid in the crevice can contain 3 to 10 times as much chloride as the bulk solution and possess a pH approaching 1. The corrosion that occurs at the interface between a titanium-alloy stem and a cobalt-alloy head is galvanic in nature and occurs when the passive oxide layer is breached. Metals or alloys that depend on oxide films or passive layers for corrosion resistance, such as CoCr and Ti alloys, are particularly susceptible to crevice corrosion.

The initiation of crevice corrosion requires, in addition to a breakdown of the passive film, the presence of an aqueous environment of body fluids. The continuation of corrosion requires that the fluids be constantly, though very slowly, replaced. One ramification of the corrosion is that fluid from inside the taper with a high metal ion content of the constituents of both the cobalt alloy and titanium alloys will be released into the host.

A continued examination of more than 650 modular femoral components tends to indicate that some designs demonstrate a higher frequency of corrosion than others, independent of the material combinations. It appears that taper geometry and quality of the fit may be dominant factors controlling the extent of the fretting that can lead to corrosion through breakdown of the passive oxide layer as previously described. However, there is still an interesting difference in the frequency of corrosion of mixed metal components versus single-alloy devices of identical taper geometry from a single manufacturer. In this recent study, 651 femoral hip prostheses, 411 of which were modular and 240 of which were one piece, were analyzed for fretting, corrosion, wear, and disassociation. Mixed-alloy components had a higher incidence of corrosion than any other combination, nearly 10 times higher than the all-cobalt-alloy systems, and 5 times higher than the all-titanium-alloy prostheses. When the total number (n=15) of retrieved all-cobalt alloy devices was matched with an equivalent number of mixed-alloy devices with similar durations from the same manufacturer, it was found that even with taper geometry and durations closely matched, the frequency of corrosion was significantly higher in the mixed-alloy group. Whether the difference in corrosion frequency is related to any galvanic effect or to the difference in modulus of elasticity of the two materials cannot be determined from the components.

Our retrieval analysis results show that the crevice provided by the tapers of modular prostheses is a harsh environment that can lead to corrosion if the metallurgy or design is not optimal. Several factors appear to be important in accelerating the rate of corrosion, including:

- breakdown of the passive film either during impaction or through subsequent fretting;
- heterogeneity of the implant alloys;
- taper configurations that allow intrusion of the aqueous environment.

Relative motion between head and stem of tapers will concurrently provide a constant breakdown of the corrosion resistant. The rapid intergranular attack of the very heterogeneous sinter-heat-treated materials as well as the relatively rapid attack of the cast-alloy heads on the titanium-alloy stems indicate that heterogeneous alloy structures will be more susceptible to rapid corrosion attack than those that are more homogeneous.

A second problem of corrosion is the potential for the long-term loss of mechanical fixation of the head to the stem. No prosthesis is known to have lost the head/stem bond by corrosion, although several retrievals have heads that were loose on their tapers. There is no reason to believe that the corrosion rate should decrease with time, and our data show that the longer the implant duration, the greater the corrosion observed. Once firm fixation is lost, fretting will add to the rate of material loss and may be expected to obliterate the pitting characteristic of this type of corrosion. Elimination of fluid from the crevice environment will eliminate the potential for corrosion, as would the return to fixed-head prostheses. However, the fact that many modular components have been in service for years demonstrating little or no evidence of corrosion indicates that proper attention to detail can result in satisfactory longevity of taper-type modular connections.

The metal backings of acetabular components can reduce the available PE thickness, often to an alarming extent. The pitting and cracking of thin PE surfaces have some similarities to tibial and patellar bearings, and creep-related deformation occurs more frequently in thin PE components.

Bartel et al. described the effect of metal backing on the stresses in PE, finding that head size was an important variable: smaller head sizes have smaller contact areas and consequently higher stresses. On the other hand, larger metal heads demand the use of thinner PE articulating surfaces. Stresses in the PE were increased enormously as thickness was reduced below 6 mm. They also examined variables of congruency between the femoral head and the PE insert as well as stiffness of the PE. They found that increasing the stiffness of the PE and reducing congruency between the femoral head and the PE insert each increased the shear stresses. They acknowledged that perfect congruency between ball and cup would be difficult to replicate, because of inherent variations in the manufacturing processing, and that fortunately, congruency increased as wear took place, resulting in lower stress and lower wear conditions.

Overall Design and Performance of Knees

Immediately following the early successes of the porous-coated hip prostheses, some failed total knee prostheses were suspected to have also been the result of problems with the cement-metal interface, and application of porous coatings to total knee components was initiated. The first such available in the U.S. were the porous-coated anatomic prostheses (PCA), a cobalt alloy prosthesis provided with a sintered, large-pored, beaded porous coating. Shortly thereafter, other manufacturers developed a variety of pore sizes of cobalt alloy bead and wire mesh titanium coatings, leading to a series of investigations to determine the optimal pore size, whether or not cobalt alloy was superior or inferior to titanium alloy, and whether a fiber mesh surface was more or less conducive to bone ingrowth than a beaded surface.

Analysis of 505 retrieved knee prostheses indicates that bone ingrowth occurs independent of pore size in the range currently available and independent of whether the coating is composed of cobalt or titanium alloy. Both beaded and wire mesh systems demonstrated the ability to permit bony fixation. Bone ingrowth of multiple screw-fixed, titanium tibial prostheses was seen with greatest frequency (75 percent), but no determination could be made as to whether this was more a function of the material composition or the type of fixation. Experience with other orthopedic prostheses suggests that mechanical fixation is the dominant variable in these systems.

The geometry of the femoral knee prostheses provides sufficient fixation and resistance to micromotion so that ingrowth of the large variety of porous surfaces appears reliable. Well-fixed patellar prostheses also demonstrate bone ingrowth, but their ingrowth interfaces appear at early risk to breakdown, due to the presence of PE wear debris generally associated with the metal-backed PE design.

The tibial prostheses evidently present a much more difficult fixation problem. The quality of bone in the proximal tibia often varies widely between medial and lateral compartments, and loads rock the prostheses both in the mediolateral as well as the anteroposterior planes. The most common appearance of tissue ingrowth of these prostheses is that of a fibrous interdigitation of varying quality. Those plateaus poorly anchored to the bone generally present the appearance of a fibrous membrane and osteoclastic activity in the adjacent bone. Prostheses that were better anchored, either by screws or central pegs, characteristically present the appearance of well-interdigitated fibrous tissue, which may be absent of any osteoclastic activity. Only those devices with very firm mechanical fixation and contact with good quality bone present bony ingrowth.

Retrieval analysis frequently revealed severe wear of the PE of the tibial insert, with the resulting wear debris often found at the interface between the metal backing and tibia. The long-term fixation of these prostheses by either bone or well-interdigitated fibrous tissue appears to be at risk to the factors released by wear debris. Early work by Willert and Semlitsch indicates that in the presence of wear debris, the host can be expected to release prostaglandins and collagenase that may well break down the interface of even well-fixed prostheses.

Material Composition

With the initiation of porous-coated total knee components, prostheses that had previously been composed entirely of PE required the application of a metal backing to which the porous coating could be applied. For cemented implants, a metal backing became desirable to permit bearing replacement without disruption of the implant fixation. Of necessity, this backing took the place of some of the previous PE thickness. The problems of patellar resurfacing are more severe than tibial or acetabular replacement, as there is insufficient room for both a metal backing and a thick PE insert without either removing sufficient bone stock that fracture of the patella becomes a very real possibility, or over-stuffing of the joint, resulting in pain and limited flexion. Therefore, many of the current designs provide a very thin PE bearing at risk for failure. Examination of components retrieved for PE failure or separation as well as those components retrieved for other reasons, often reveal the presence of particulate PE wear debris at the margins of the bone ingrowth surface, leading to concerns for long-term breakdown of this interface.

The metal backing typically reduces the space available for PE by 3–4 mm. As a result, the PE thickness is always less than the 6 mm cited as necessary for nonconforming surfaces by Wright and Bartel. At the fixating lugs and margins of the component, the PE thickness may be less than 3 mm. Additionally, creep reduces the PE thickness, thereby further increasing the stresses causing early fatigue failure.

Testing of total knee components indicates that patellofemoral articulation produces the greatest contact stresses at higher flexion angles as a function of increased resultant loads. There is also a concomitant reduction in contact area as the patella moves into the intercondylar notch, thus losing support at the apex and shifting contact to two points at the periphery. The increase in contact stress in flexion can be significant. Most dome-shaped components are designed to have their greatest conformity in extension. Additionally, designs with convex condylar and patellar geometries can produce point contact that results in very high contact stresses. To avoid high contact stresses in the patella, it is important that components be designed to match femoral geometries in both extension and flexion. Drawing the metal of the patellar groove further into flexion serves to increase the contact area and decrease the contact stresses in this region. In some instances, however, this may not leave enough space to preserve the posterior cruciate ligament. Another way to increase contact area in flexion is to modify the dome of the patella component so that it more closely matches the curve of the femoral condyles in the frontal plane.

Reports of the high incidence of PE failure of metal-backed patellar components rekindled interest in cemented, all-PE designs. The trend was based on the false assumption that the metal backing was the source of all problems and that all-PE components, relatively independent of design, would provide improved performance simply because of increased PE thickness. Our analysis of 104 retrieved patellar components, combined with high-resolution, contact stress testing, indicates that surface geometry is as critical to performance as PE thickness. Contact stress analysis indicated that under loads of 4× body weight, all but the most congruent designs produced stresses in the PE considerably in excess of its yield strength. The least congruent designs produced more than twice the contact stress of the most congruent designs.

In the early 1980s, the possibility that aseptic loosening, the major cause of total knee failure, was influenced by the flexibility of the all-PE tibial component was examined. Researchers concluded that metal-backed components would reduce the stress in the supporting bone and bone cement compared to all-PE designs. In 1985, the importance of PE thickness and geometry was analyzed in several separate studies, and researchers agreed on a recommended minimum PE thickness of 8 mm.

This PE thickness, when combined with a metal backing, results in a relatively thick component requiring significant bone resection. Surgeons have been taught to resect as little bone as possible and manufacturers realize they must sell what the market demands. Therefore, many of the current designs provide surgeons with less than the recommended minimum PE thickness.

Our analysis indicated that the vast majority of failed, metal-backed tibial components were of a modular type and had been fitted with the thinnest, or close to the thinnest, available PE inserts. This is most likely the result of the surgeon's desire to resect as little tibial bone stock as possible, combined with a lack of retrieval data documenting the potential for failure of thin PE inserts caused by high-contact stress. While a study by Goldstein has shown that the quality of tibial bone decreases with increasing depth of resection, a careful analysis of the data indicates that these changes are small within the first 2 cm of the tibial surface. Therefore, it is not unreasonable to suggest that surgeons sacrifice several millimeters of bone to enable the insertion of a thicker PE bearing.

High stresses in thin PE bearings in noncongruent knee designs are predictable. Further, our analysis of retrieved tibial components revealed that the less congruent, higher contact stress-producing devices presented greater wear. Finite element analysis demonstrated that the stress intensity in the PE decreases dramatically with increasing thickness. An increase of as little as 4 mm of PE (from 3 to 7 mm) reduced the maximum Von Mises stress by as much as 27 percent, and the maximum contact stress by 14 percent. Retrieval analysis also revealed that the fixation of the PE inserts to the metal backing does not eliminate motion between the two, and that an additional, initial articulation is provided in many of these modular prostheses. Over time, the PE often creeps significantly: more than 1 mm of creep into screw holes was seen in some components. While this creep may eventually help the PE to lock in place, its extent, and the potential for screw/PE contact and fretting wear, raises additional concerns.

Thin PE tibial inserts and designs with low conformity contribute to high stresses within the PE, increasing the risk for fatigue failure. Additionally, surface heat treatment appears to be a factor in the extent of delamination in high-stress designs. Interestingly, however, even the most congruent designs with the thickest PE bearings sometimes fail by fatigue of the PE after years in service. The PE of these components appeared yellowed and brittle as well as cracked and delaminated, leading us to the conclusion that the white, highly ductile PE from which the components were fabricated changed with time through some mechanism.

Laboratory testing of total knee components indicates that many designs produce contact stresses that exceed the yield strength of ultra-high molecular weight PEs (UHMWPEs). Stress on the bearing material in the knee is more complex than in the hip, because the kinematics of the knee articulating surfaces include both rolling and sliding, while the hip only slides. The rolling/sliding motion of the knee results in cyclical tension and compression at the articulating PE surface and shear below the surface. Typically, the intensity of these stresses is directly influenced by the contact stress at the surface of the bearing, which is in large part a function of implant design and surface conformity, the outcome of which is directly related to the quality of the PE.

Most knee designs are of the fixed-bearing configuration in which the PE-articulating surface is firmly affixed to bone. Unfortunately, in a fixed-bearing knee, low contact stress resulting from increased conformity, limits flexibility in terms of alignment (specifically rotation), mating of components of different sizes, and implant positioning. This typically leads to a compromise in which the conformity, and therefore the contact area, is reduced to avoid overconstraining the joint, which might lead to loosening. Just how much contact area to sacrifice and how best to achieve that compromise remains a matter of contention, as evidenced by the myriad of different designs available to the surgeon.

Although highly conforming designs produce lower contact stresses through increased contact area, they also may produce excessive stresses at the bone-prosthesis interface, running the risk of long-term loosening. Fully conforming devices match articulating geometries in both the frontal and sagittal planes, producing area contact, while moderately conforming geometries typically match profiles only in one plane, producing line or point contact. The frontal plane profiles in moderately conforming tibiofemoral designs are either curve-on-curve (CoC) or flat-on-flat (FoF). Moderately conforming patellofemoral designs are typically dome-shaped, producing line contact in extension and point contact in flexion. In previous works, testing of virgin components demonstrated that fully conforming tibiofemoral and patellofemoral components produced dramatically lower contact stresses than their moderately conforming counterparts. In the tibiofemoral designs, no difference was seen between the FoF or CoC designs in neutral alignment, but the latter were more forgiving of varus-valgus and rotational malalignment than the FoF geometries. In the patellofemoral designs, anatomic fixed bearings proved to be much more sensitive to rotational malalignment than the dome-shaped configurations.

Clinical correlations have shown that fully conforming tibiofemoral and patellofemoral designs result in a lower incidence of pitting, delamination, and cracking than less conforming devices. Examination of retrieved, fully conforming tibiofemoral designs with mobile bearings showed burnishing of the metal articulating surface, indicating that the PE bearings are, in fact, moving with respect to the tibial baseplate. It is this motion that permits the fully conforming tibial component to avoid transmitting high shear forces to the bone-prosthesis interface. Additionally, these designs are very forgiving of rotational malalignment. The absence of significant scratching or burnishing on the metal articular surfaces of most of the mobile patellar bearings, however, suggests that these devices may not actually be rotating in service. The principal advantage of the mobile bearing in the patella may instead be that it is extremely forgiving of variations in surgical alignment and, once the components are engaged, these devices may simply rotate to a preferential alignment and stay there.

In tests of 33 total knee components of varying manufacturers and designs, we found that several designs produced contact stresses above the uniaxial yield strength of UHMWPE (21 MPa). Given these high contact stresses and the data relating high contact stresses to component failure, it is worth asking why more components do not fail *in vivo*. There are probably a number of reasons for this. Contact stresses that exceed the uniaxial yield strength of PE do not necessarily imply that the shear stresses, which are responsible for material failure, are above the yield strength in shear. But even if the shear stresses are above yield, yield in PE is characterized by plastic deformation and not by brittle failure. Components tested in the laboratory are often loaded to points well above the yield strength without any readily apparent catastrophic effects: obviously, they can exceed the yield stress some finite number of times before noticeable damage begins to appear. Because of individual variations in activity and gait alteration, it is possible that many components do not experience large, cyclic loads frequently enough to accumulate damage. Total knee recipients may place less stringent demands on their prosthetic knees by favoring them or by using aids such as canes or walkers. They also may limit or aid the deep flexion activities, such as rising from a chair or walking up stairs, that produce higher stresses. In reality, most prostheses probably experience loads well below three times the body weight for most of their service. It also has been shown that at higher flexion angles the patellar tendon engages the femur and carries almost half of the resultant patellar load, thus reducing the severity of the load on the articular patellar surface.

Variations in the material properties of the PE as a result of the extent of consolidation also may dramatically influence the susceptibility of the bearing to fatigue failure. It may be that the variations in failure rates for designs with similar contact stresses are due to variations in PE quality. A combination of a low contact stress design and high-quality material may be the ultimate prescription for long-term survival of PE bearing surfaces in the knee.

Polyethylene Quality

Improved PE in the form of UHMWPE has been the material of choice for the past two decades. Its high abrasion resistance and impact strength, along with its toughness, ease of fabrication, and nontoxicity seemed to ensure that bearing surfaces fabricated from this material would serve well in hip and knee prostheses. Unfortunately, there is little documentation in the orthopaedic literature regarding the uniformity, material properties, or quality of the PE used in these applications. Recently, the increased frequency of fatigue-related wear damage, the failure of PE bearing components, and the problems associated with the resulting wear debris, have shifted the focus of current research to improving the wear characteristics of the PE components.

As part of our analysis of retrieved acetabular components, a combination of reflected and transmitted light was used to examine the inner surface of the PE. In doing so, it became obvious that many specimens contained internal flaws in the shape of spherical voids that can be seen at high magnification as isolated particles that did not fully fuse to the surrounding material. Because PE is more vulnerable to oxidation when processed at temperatures above 150 °C, manufacturers keep the processing temperature below this level. It seems, however, that the temperature being used is often too low to completely melt all the particles. In one study, 79 percent of the PE inserts examined showed voids, 45 percent in high concentrations. These occurred in almost all types of acetabular components and were often associated with the presence of cracking. With further inspection, the voids were found to be relatively uniform and were not a surface phenomenon.

Examination of more than 300 components for wear and the extent of the fusion defects, however, revealed little correlation between the two, possibly because a second phenomenon, a white band that appeared to follow the contours of the most highly damaged components, was a more dominant variable. Laboratory testing revealed differences in the static properties of samples with and without defects with large samples indicating a reduction of strength and ductility of up to 20 percent in some samples with defects. It is likely that the defects play a greater role in fatigue situations that have not been tested in the laboratory to any significant extent.

The white band, a zone of material more opaque than the surrounding PE, became visible due to the light scattering from the microcracking generated during the sectioning process: it follows the contour of the component at a depth of approximately 1 mm. The location of the band varied in retrievals, appearing most frequently in the flange region and on the articulating surface, and least frequently on the surface directly apposed to a metal backing.

Two never-implanted, 14-year-old components, still sealed in orignal packaging, were examined. They were from the same manufacturing lot and differed only in that one was gamma sterilized in air (GSA) and the other was never sterilized. Only the GSA component had the band. This pair of components confirmed the effect of GSA seen in retrievals.

To further investigate this phenomenon, we selected 150 PE acetabular components, sterilized by various methods including GSA and ethylene oxide (EO), from a retrieval base of >600 to represent a range of manufacturers and *in vivo* durations. The heavily damaged retrievals with rim-cracking and delamination were GSA; none of the EO-sterilized components showed either rim-cracking or delamination. Correspondingly, none of the EO-sterilized components showed the subsurface white band, while 68 percent of the GSA components did. Upon further investigation and discussion with the manufacturers, components exhibiting the band were confirmed to be GSA and most were over 3 years post-sterilization. Of the retrieved components showing delamination, 95 percent had the band, and it was present in 100 percent of the components showing cracking-type damage. Statistical contingency tests confirmed that both cracking and delamination were highly dependent on the presence of the subsurface white band. Other modes of wear did not significantly correlate with its presence.

Measurement by infrared spectroscopy of oxidation (CO area/mil thickness) versus depth into components revealed that the GSA components with the subsurface white band have substantially elevated oxidation levels. Previous research supports the idea of GSA-induced oxidation: free radicals formed by irradiation persist for years, reacting with oxygen over time. Oxidation has a great effect on the performance of the material. Mechanical testing of white-banded components reveals a marked decrease in elongation and ultimate tensile strength (UTS). Stresses applied by normal service loading and the existence of the interface between ductile and brittle material may eventually be a source of delamination of hips. Although delamination is currently not a predominant mode of failure in hips, this subsurface loss of elongation would be critical in knee components where maximum stresses occur subsurface.

As with hips, analysis of 182 retrieved, and 40 never-implanted tibial components revealed that 63 percent of the retrievals and 90 percent of the never-implanted components exhibited the subsurface white band. Of these, all had been GSA and were at least 3 years post-sterilization. Statistical contingency tests again confirmed that component cracking and delamination were highly dependent on the presence of this subsurface opaque band. The band was present in 89 percent of the components showing signs of cracking and in 91 percent of the components with delamination.

Mechanical testing revealed the biggest changes for GSA components. UTS and percent elongation were significantly less than the ASTM specifications (27 MPa and 200 percent, respectively) in the white band region of these components. Percent elongation was nearly zero in the opaque zone, indicating severe PE embrittlement. Tensile testing of the microtomed vertical cross sections confirm a difference in properties as a function of depth. Failure of the subsurface white band region before failure of either the clear outer layer or the center zone indicates reduced ductility of the subsurface zone relative to the others. Sections taken without including white-band material stretched much further before failure.

The band was found in sections cut with a microtome but not in those cut with a diamondimpregnated abrasive disk, indicating the importance of sample preparation in such testing. Vertical sections prepared with the diamond-disk did not have any cracks in the subsurface region, but since they also failed first in the this region, they confirm a difference in ductility as a function of depth without the confounding effects of microtome-induced microcracks.

Earlier studies have reported high subsurface shear stresses at the same location as the white band. Our cyclic testing confirms what clinical studies indicate: fatigue occurs preferentially in the subsurface region of PE tibial components. White-banded, GSA components failed by fatigue after only a few hundred cycles, compared to 10,000 cycles for band-free components.

From these investigations, we determined that GSA acts as both an initiator and an accelerator of PE oxidation and that there is a need for improvement in the GSA process used by the orthopaedic implant industry. Sterilizing in an oxygen-free atmosphere has potential for reducing the immediate effects of this oxidation. Also, low-dose radiation appears to cause less oxidation than higher dosages, probably by breaking fewer PE chains, thereby reducing the number of oxidation sites. Furthermore, non-gamma radiation sterilization techniques such as EO and Gas Plasma appear to have little effect on oxidation.

In addition to providing increased longevity of all prostheses using PE as a bearing surface, implementation of these modifications to sterilization procedures may actually eliminate the fatigue failure of PE tibial components, now the most common mechanism for the breakdown of total knee prostheses.

CONCLUSION—Understanding of the complexities of successful joint replacement has improved substantially since 1988. While fixation issues are still a major concern, many more potential problems have been identified. Debris generation from PE wear is considered the biggest one today; other problems result from attempts to customize implants for a more individualized fit. Modular implants, while allowing an immediate custom fit, introduce the possibility of component corrosion, fretting, screws loosening, and so forth, and screw holes can provide pathways for the migration of PE and other types of debris. Identification of such potential problems with various designs has been an important function of retrieval analysis.

Our retrieval rate has increased by well over a factor of two during the decade of VA funding. We have published more than 10 papers and several book chapters, and have presented results of the Center's research in more than 50 papers and presentations at the American Academy of Orthopaedic Surgeons and other pertinent meetings. In addition, our implant retrieval lab is visited on a regular basis by orthopedic surgeons and the heads of research and development of orthopaedic implant manufacturers interested in the performance of these devices.

[203] THE EFFECTS OF TRANSVERSE, ANTERIOR COLUMN, AND POSTERIOR COLUMN ACETABULAR FRACTURES ON THE STABILITY OF THE HIP JOINT

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PURPOSE—Post-traumatic arthrosis may result from unreduced acetabular fractures. This is especially true if the fracture crosses a portion of the acetabulum necessary for weightbearing. However, the exact portion of the acetabulum necessary for normal weightbearing is not known. At the very least, normal weightbearing requires a stable hip joint. Thus, an acetabular fracture that affects hip joint stability can be assumed to involve an important weightbearing area. Such a fracture, if left unreduced, most likely would lead to arthrosis. The purpose of this study was to assess how various transverse, anterior column, and posterior column acetabular fractures affect hip joint stability.

METHODOLOGY—A total of 24 fresh-frozen cadaver hip joints were used in this investigation. Each was mounted in a mechanical testing machine so that compressive forces of various magnitudes could be applied. The femur was mounted vertically on a freely moving instrumented x-y displacement table. Stability of the hip joint depended upon only the intrinsic stability of the articulation between the femur and the acetabulum. The acetabulum was mounted in a fixture that allowed simulation of the various fractures and allowed positioning of the joint so that the magnitude and direction of the peak forces seen during normal gait could be applied. For each of the fracture types, the specimens were loaded in compression four times at each of three loads (800, 1,200, and 1,600 N). Each specimen was first tested intact, and again following each of the various simulated fractures. Simultaneous recordings were made of the load, actuator displacement, and translation of the femur. A hip was considered stable if no dislocations occurred over the four loading cycles.

Transverse acetabular fractures (OTA classification 62-B1) were evaluated in 12 specimens. Each specimen was tested with successive transverse fractures having roof-arc angles of 60, 50, 40, 30, and 20°. The roof-arc angles were determined radiographically. Anterior column fractures (OTA 62-A3) were evaluated in six specimens. For each specimen, very low, low, intermediate, and high fractures were tested successively. Posterior column fractures (OTA 62-A2) also were evaluated in six specimens; only very low posterior column fractures were tested.

RESULTS—All 24 hips were stable when loaded intact to 800, 1,200, and 1,600 N. For the transverse fractures, for each of the applied loads, the number of stable specimens decreased with each successive fracture. For these fractures, stability was significantly affected by both the location of the fracture (roof-arc angle) and the magnitude of the applied load. For the anterior column fractures, all specimens with very low, low, and intermediate fractures remained stable throughout all tests. With high anterior column fractures, 33 percent were unstable when loaded to 800 N, 67 percent were unstable when loaded to 1,200 N, and all were unstable when loaded to 1,600 N. Overall, the posterior column fractures were the least stable. All six specimens were unstable with the simulated very low fracture (exiting the posterior column just superior to the ischial spine).

Anterior column fractures were more stable than expected. No specimens were unstable unless the fracture was of the very high type. Fractures at the base of the pubic rami did not affect stability. Only fractures that exited through the iliac crest caused instability. This suggests that fractures at the base of the pubic ramus may be less important then previously thought. Posterior column fractures were much less stable than expected. Even low fractures, that is, fractures at the level of the ischial spine, rendered the hip unstable in all six specimens, even at the lowest applied load.

The results of this study have direct implications in the treatment of anterior column and T-type fractures. Based on these results, currently only anterior column fractures that exit through the iliac crest are treated surgically. For T-type fractures, the posterior column is the greater concern, and requires reduction and fixation even if the fracture is very low. The anterior column portion of the fracture is of concern only if it very high.

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Evaluation of hip stability after simulated transverse acetabular fractures. Thomas KA, Vrahas MS, Bearden CM, Reid JS. Clin Orthop 1997;340:244–56.

C. Knee Implants

[204] MODIFICATION OF POLYETHYLENE TO IMPROVE THE WEAR PERFORMANCE OF JOINT REPLACEMENT PROSTHESES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A877-RA)*

PURPOSE—This study is an investigation of the effects of molecular orientation on the wear behavior of ultra-high molecular polyethylene (UHMWPE) used in total joint replacement prostheses. The long-term goals are to determine processing conditions for UHMWPE that optimize its performance in total joint replacement prostheses.

METHODOLOGY—Ram-extruded rod stock of medical grade UHMWPE (GUR 4150) was obtained from commercial sources. Slabs were machined from the stock, heated to 170 °C in a vacuum oven and slow cooled to room temperature. Each specimen was characterized using wide angle X-ray diffraction (WAXD), small angle X-ray scattering (SAXS) and differential scanning calorimetric (DSC) analyses.

The slabs were subjected to plane strain compression, using a channel-die compression apparatus. Selected samples were chosen for wear tests on the three orthogonal surfaces of the rectangular bars produced by channel-die compression. We define these surfaces as loading or LD surface (surface normal along loading or LD direction), constrained or CD surface (surface normal perpendicular to the walls of the channel-die) and flow or FD surface (surface normal along the flow direction).

PROGRESS—We have essentially completed all the experiments proposed in this study. Approximately 35–40 unoriented slabs were prepared for the morphological and wear studies. Each slab was snugly fitted into a channel-die preheated to 90 °C and compressed using an Instron tester to varying compression ratios (CR). We define CR as the ratio of initial height of the slab to the final height of the compressed (or oriented) slab. Each bar was prepared with a different initial height so that the dimensions after compression were identical. Samples with CR of 1.4, 1.95, 3.2, 4.0, and 5.6 were subjected to SAXS, WAXD, and DSC analyses to study evolution of crystallographic orientation.

Rectangular bars with selected CR of 2.7 and 1.7 were wear tested using a 4 station reciprocating (sliding) wear tester. Wear tests were performed on the LD, CD, and FD surfaces. Each test was performed by sliding cylindrical cobalt-chromium alloy pins on flat UHMWPE bars with an applied load of 90.7 kg. Bovine serum was used as the lubricant.

RESULTS—There was a 5 percent reduction in the percentage crystallinity (or density) in specimens with a CR above 2.0. SAXS and WAXD characterization showed a substantial degree of molecular orientation above CR of 1.4. The degree of orientation increased monotonically until CR of 6.0, after which brittle fracture occurred.

Wear tests of samples with a CR of 2.7 and 1.7 were compared to standard, uncompressed UHMWPE (CR=1.0). At a sliding distance of 14,813 m, the wear volume of standard UHMWPE normalized by applied load was (0.97±0.31)E-7 mm^3/N. The volume of wear particles on LD, CD, and FD surfaces under identical conditions of wear was in the range of (1.27–0.79)E-7 mm^3/N. This reveals that molecular orientation does not substantially affect wear rates in UHMWPE.

FUTURE PLANS/IMPLICATIONS—Our results suggest that wear of UHMWPE is governed by morphology at the micrometer length scale rather than the nanometer level morphological parameters, such as degree of molecular orientation. We plan to use a combination of processing conditions and chemistry to improve consolidation of the micrometer-sized resin particles to improve wear performance of UHMWPE prosthetic components.

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[205] EFFECT OF COMPONENT PLACEMENT ON THE PATELLOFEMORAL JOINT KINETICS WITH TOTAL KNEE ARTHROPLASTY

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PURPOSE—This research is quantifying the effects of component alignment in total knee arthroplasty (TKA) on patellofemoral joint kinetics and general knee kinematics. The goal is to increase long-term survival of knee replacements by determining the required accuracy in the placement of these components and by evaluating joint replacement component selection.

METHODOLOGY—Cadaveric knee specimens are mounted in a knee simulator after careful specimen preparation. Knee arthroplasty is performed with components from Zimmer, Inc., using standard sizing techniques and recommended instrumentation.

A specially designed device anchors the femur in the knee simulator and sets the amount of internal-external rotation of the femoral component. Using the wormgear drive mechanism in the device, internal-external rotation of the component can be set to any desired orientation with an accuracy of 0.25 degrees without re-opening the joint capsule.

After recording the native thickness, the patella is cut in the recommended way, removing the articular surface. A load cell, mounted on the anterior patellar face, supports a plate on which the patellar prosthesis is mounted. This support plate has holes for fixation of the patellar prosthesis at desired lateral-medial positions and also adjusts to restore the native patellar thickness. The joint capsule is closed and a nylon strap is sutured to the central quadriceps tendon. The knee is placed in the simulator with the nylon strap attached to a hydraulic actuator.

All patellofemoral kinetics and tibiofemoral kinematics are recorded. The load cell measures all six components of load on the patella and two instrumented spatial linkages track all six degrees of freedom of the movement of the patella and tibia with respect to the femur. The actuator of the knee simulator drives the knee through a flexion-extension cycle of 105°. The femoral and patellar components are repositioned after each test and a lateral retincacular release is performed after all alignments have been studied.

PROGRESS—Ten specimens have been tested with all combinations of femoral external rotation of 0, 2.5, and 5° and patellar button placement at the geometric center and at 3.75 mm medial to the geometric center for a posterior cruciate sparing TKA. To compare the effects of TKA system selection and component placement, an ongoing study has tested four with both a system that retains, and a system that sacrifices, the posterior cruciate ligament.

RESULTS—The combination of 2.5° of femoral component external rotation with patellar button medialization reduced the lateral-medial shear force on the patella. This combination would therefore reduce any tendency of patellar subluxation. All combinations of small changes in femoral and patellar component alignment provided generally very good patellar tracking, indicating that implantation could vary and still maintain good short-term surgical outcome.

Tibial kinematics were altered by variation in femoral component alignment, but not by patellar button placement. Femoral component rotation affected tibial rotation at small flexion angles and tibial varus-valgus rotation at large flexion angles. At larger flexion angles, the tibio-femoral contact becomes more posterior on the femoral condyles. This increasingly posterior contact causes external femoral component rotation to effect increasing tibial varus orientation. No short-term problems in functionality occurred, but potential long-term implications may exist.

A lateral retinacular release had essentially no effect on kinetics or kinematics. All specimens tracked well before and after the procedure.

IMPLICATIONS—A combination of small amount of external femoral component rotation and patellar button medialization provides good patellofemoral kinematics and load transfer for this TKA design. Tibiofemoral kinematics are clearly affected by femoral component rotation.

FUTURE WORK—Testing with posterior cruciate retaining and sacrificing components will be continued and will include variation in tibial component alignment.

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[206] EFFECT OF INTRA-ARTICULAR IMPLANTS ON THE HEALTH OF THE KNEE JOINT

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Sponsor: *Smith & Nephew Richards*

PURPOSE—Retrograde femoral nails inserted are gaining increasing popularity. After implantation, the device is exposed to the joint environment. The purpose of this study is to established the long-term effects of these implants on the health of the joint's structures.

METHODOLOGY—Specially modified stainless steel screws were inserted through the intercondylar notch into the femora of 18 New Zealand White rabbits. The contralateral limb underwent a sham insertion, with every procedure duplicated, including reaming and threading, with the exception of the insertion of the device. Knees are harvested in groups 6 wks, 3 mo, 6 mo, and 1 yr postimplant and examined histologically for changes in the cartilage, sibchondral bone, and synovium.

PROGRESS—To date, all implants and harvestings have been performed; gross examination of the 6 wk, 3 mo, and 6 mo knees shows no evidence of joint arthropathy. Currently, we are processing and evaluating histological specimens to document whether there are differences between the implanted and sham-operated knees.

D. Arthritis

[207] IMPACT-INDUCED POST-TRAUMATIC ARTHRITIS MODEL

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Sponsor: *AO Foundation*

PURPOSE—Post-traumatic arthritis is a rapid joint degeneration which occurs as a result of a traumatic event. The purpose of our research is to develop a model to predict the impact stress magnitudes that result in post-traumatic arthritis.

METHODOLOGY—An impact tower is used to guide a falling mass that delivers a blow of specific energy to an impactor instrumented with strain gages to record force. Bone cement is used to create a custom impactor to apply uniform stress over the impacted area. The area of impact is measured by making an imprint onto a sheet of paper with a wax marker. Accurate estimation of impact force and area lead to an estimate of impact stress, believed to be the most important factor in predicting the occurrence of post-traumatic changes.

PROGRESS—To date, an *in vitro* rabbit model was used to develop the impact tower instrumented to record impact force, along with the technique to fabricate custom impactors which provide uniform stress to a given area of the rabbit's femoral condyle. A pilot *in vivo* study was performed to show that histochemical changes associated with the early development of arthritis could be found in rabbits 6 wks following an impact. Currently, we are evaluating histological specimens from 36 rabbits whose knees have been impacted and who have been kept up to 1 yr post-impact with aim to document whether there are long-term changes in the impacted femoral cartilage.

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E. Low Back Pain

[208] EFFECT OF SURGICAL PROCEDURES ON THE STABILITY OF THE LUMBAR MOTION SEGMENT

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PURPOSE—Many surgical procedures of the lumbar spine, such as laminectomy and discectomy, require removal of tissue from the motion segment. When large amounts of tissue are removed, the stiffness of the motion segment is reduced to a degree that there is an abnormal response to an applied load. To compensate for this decrease in stiffness, fusion surgery is sometimes performed. At the present time, there is a clinical controversy about when a fusion should or should not be performed. The purpose of this research is to quantify the segmental instability resulting from the commonly used surgical techniques of facet and disc resection through a combination of experimental and analytical techniques.

METHODOLOGY—We performed experiments on human cadaveric lumbar spine specimens to determine the effects of surgical procedures on the 3-D load-displacement behavior of lumbar motion segments. The experiments simulated different combinations of surgical procedures, including unilateral and bilateral facet removal and disc denucleation. Next, we validated a finite element (FE) model of a lumbar segment by modeling the experimental simulations of these procedures. Finally, the validated FE model was used to conduct a detailed parametric study of the effects of the surgical procedures on the change in stiffness of the lumbar motion segments.

PROGRESS—We have completed a major portion of the tests on lumbar specimens to determine the effects of different surgical procedures on the load-displacement behavior. The geometric shape of a vertebra-disc-vertebra segment was generated from a serial CT scan. The nonlinear FE analyses have been conducted. The model was first used to analyze the effect of graded unilateral facetectomies (25, 50, 75, and 100 percent) on the stiffness of the spine. In addition, at each level of graded facetectomy, nucleotomy was also performed to understand the combined effect of graded facetectomy and nucleotomy.

RESULTS—A large increase in flexibility was observed for all loading modes when as little as 25 percent of the facet was resected and a nucleotomy performed. If the surgical intervention was restricted to facet joints only, this sudden increase in flexibility was observed after 75 percent of unilateral facetectomy. The breakpoint at which there is a sudden increase in flexibility depended on the loading mode. Torsional and flexion moments produced a sudden increase in flexibility after 75 percent of a facet was removed, while the rest of the physiological loads showed a breakpoint after complete unilateral facetectomy. When nucleotomy was combined with graded facetectomy, all loading modes except torsion increased in flexibility. Clinically, these results show that a unilateral 75 percent facetectomy alone can be done without much effect on the stiffness of the spine. If facetectomy is combined with nucleotomy even removal of 25 percent of facet is enough to cause an increase in motion of the segment.

FUTURE PLANS/IMPLICATIONS—Additional experiments will be run as needed to improve the statistical significance of the experimental study. The information generated in this study will be used as a basis for developing recommendations concerning when to fuse and when not to fuse.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[209] A MINIMAL EFFORT TEST FOR PATIENTS IN PAIN USING THE BACK ANALYSIS SYSTEM

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PURPOSE—Previous analysis of surface EMG signals of the lumbar back muscles assessed with the Back Analysis System (BAS) has been based on the concept of fatiguing the muscles by investigating the behavior of the initial median frequency and the rate of decrease of the median frequency during fatiguing contractions. The use of such procedures may not be well suited for subjects in acute phases of injury due to obvious hesitation and fear of re-injury, making the assessment of a reliable endurance effort unreliable. In this project, new force insensitive parameters are being investigated that instead reflect aspects of load sharing by describing spectral interactions and imbalances between pairs of muscles of the lumbar back.

The long-term objectives of this proposal are to: provide clinicians and researchers with a procedure to objectively quantify muscle impairment associated with low back pain in previously non-testable subjects with acute pain so that specific early interventions can be provided thus minimizing the risk that subjects reach a chronic injury state. Also, we seek to provide clinicians with objective information regarding the transition of an injury from an acute to a subacute phase thus assisting in decisions concerning treatment for the individual patient.

METHODOLOGY—A total of 80 controls and 70 LBP patients in an acute phase of injury will be tested. Surface EMG activity will be recorded from six muscle sites of the lumbar back while the subject performs brief isometric incrementing stair case contractions up to 80 percent of ideal body weight in the BAS. The behavior of ratios between spectral properties in contralateral as well as ipsilateral pairs of muscles of the lower back are being investigated. New parameters with clinical relevance describing segmental imbalances and bilateral compensations in spectral parameters have been introduced. A series of questionnaires will be administered to subjects to assess fear-avoidance strategies in different phases of the injury.

PROGRESS—A clinical version of the BAS system has been completed and installed with new software for data collection and database storage. Software development for data analysis to study the behavior of load-sharing parameters on the BAS is near completion. Recruitment and screening of LBP subjects is in progress; 15 controls subjects have been tested.

PRELIMINARY RESULTS—Results thus far have suggested that imbalances are present in both persons with LBP and controls. However, imbalances appear to be compensated across lumbar levels for the latter but not for the former.

FUTURE PLANS—Scheduling and testing of subjects is currently in progress. Testing of controls continues. Development of software for extraction of EMG-based parameters is progressing and should be finished by the end of 1997.

RECENT PUBLICATIONS FROM THIS RESEARCH

Development of new protocols and analysis procedures for the assessment of LBP by surface EMG techniques. Oddsson LIE, Giphart JE, Buijs RJC, Roy SH, Taylor HP, De Luca CN. J Rehabil Res Dev 1997;34(4):415–26.

Development of new protocols and analysis procedures for the assessment of LBP by surface EMG techniques. Oddsson LIE, Giphart JE, Buijs RJC, Roy SH, Taylor HP, De Luca CN. J Rehabil Res Dev 1997;34(4):415–26.

[210] BACK EXERCISE PRESCRIPTION AND IMPLEMENTATION BY SURFACE ELECTROMYOGRAPHIC PROCEDURES

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PURPOSE—The purpose of this project is to develop a low back pain (LBP) exercise procedure for restoring muscle impairments classified by the Back Analysis System (BAS). This study will considerably advance the BAS technique to include the prescription and implementation of muscle-specific, individualized exercises to improve strength and endurance.

METHODOLOGY—Phase I of the study will focus on modifying the BAS to implement isometric exercises for reconditioning impaired back extensor muscles. Isometric and isotonic exercises will be developed outside of the BAS to selectively recondition impaired muscle groups. The use of a portable 2-channel EMG unit will be evaluated to enhance muscle activation during the performance of the exercises outside of the BAS. Phase II of the study will evaluate the effectiveness of the exercise protocol by comparing treatment outcomes in patients with LBP randomly assigned to either an experimental exercise group, a generalized strengthening exercise group, or a control group without supervised exercise.

PROGRESS—We have completed the modifications of the BAS to implement isometric exercises via EMG and force feedback and are currently evaluating its capabilities among test subjects. We have also defined an exercise protocol of trunk exercise strengthening and control based on paraspinal surface EMG measurements to verify patterns of muscle activation and spinal stabilization. These exercises will be implemented among the LBP clinical population utilizing portable EMG biofeedback units. A BAS system has been set up at our clinical site and we have commenced the randomized longitudinal component of the study to evaluate the efficacy of the experimental exercise program vs control exercise.

PRELIMINARY RESULTS—We are currently working on all aspects of Phase I. We have made considerable modifications to the BAS software in preparation for real-time visual feedback of EMG signals and trunk extension forces during the performance of isometric exercises. Tests have been conducted upon control subjects to determine the extent to which the technique can isolate functional regions of paraspinal muscles that correspond to the to the EMG electrode locations. Subjects have been tested during the execution of a variety of floor exercises commonly prescribed for progressive lumbar stabilization. Subjects are instrumented with surface EMG electrodes during the performance of these exercises to record the activation patterns among eight muscles of the trunk.

FUTURE PLANS—We are continuing the collection of data at the clinical test site and will evaluate the results upon completion of EMG and outcome data.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Time-frequency analysis of EMG signals from repetitive lifting. Roy SH, Bonato P, Kedzierski AS, et al. Proceedings of the 11th International Congress of ISEK. 1996 Oct, Enschede, Netherlands.

[211] THE QUANTIFICATION AND INTERPRETATION OF BACK MOTION AS AN EVALUATIVE TOOL IN LOW BACK DISORDERS

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PURPOSE—Low back disorders (LBD) are extremely common and limit the ability of millions of Americans to lead productive lives and engage in meaningful work. Impairment ratings of LBD can vary by as much as 70 percent using current systems. Diagnoses and classification schemes are rarely based upon quantitative indicators, and we are unable to easily assess and diagnose LBDs. It is important to evaluate LBDs quantitatively, so that proper treatment can be administered and to minimize the risk of exacerbating the problem.

METHODOLOGY—Studies were performed that quantified 3-D trunk motion characteristics as a function of asymmetry for controls and persons with LBD to classify those with LBD compared to those without; to test alternative testing protocols; to develop a sincerity-of-effort test; and to benchmark longitudinal recovery.

Four studies have been performed or are in the process of being performed. In the *Task Asymmetry Protocol,* subjects bend forward and back upright while controlling their twisting position at five asymmetries including: 0, 15° right and left, and 30° right and left. A new *Cardinal Plane Protocol* was developed where subjects performed three separate tasks: bending forward and back, bending side to side, and twisting right to left. They were instructed to move as fast as they felt comfortable in a comfortable range of motion. The *Sincerity-of-Effort* aspect of this project has been developed in the past year. The theory is that unless the test can distinguish sincere effort from the subject, the classification of control and subject may be erroneous. Subjects are required to perform each task twice, once sincerely and once pretending their symptoms are worse or, in the case of controls, pretending they have back pain. The *Preliminary Longitudinal Phase* evaluates subjects every 2 wks during the first 3 mo of injury, regardless of treatments and/or visits for a total of six visits.

PROGRESS—The *Task Asymmetry Protocol* has a total of 717 subjects (350 controls and 367 LBD). A model was developed using a training data set to distinguish between the two groups. The best model for classifying them included: ability to perform each task, twisting range, sagittal range of motion at zero, sagittal extension velocity at zero, sagittal extension acceleration at zero and lateral range of motion at zero. The results of the discriminant function analysis show a 9 percent test set error.

The *Cardinal Plane Protocol* elicits dynamic tasks in the transverse and coronal planes of the body, which were not in the asymmetry protocol. The theory behind this protocol is that biomechanically, a LBD may affect one plane of motion more than another, depending on the nature of the injury. Three separate models have been developed using discriminant function to distinguish the two groups in each task separately.

The *Sincerity-of-Effort* thus far has 96 controls with at least 10 males and 10 females in 10-yr age groups from 20–59. All LBD subjects tested have been within these age groups. Two models were developed, one for each gender. The sincere men were correctly classified in 86 percent of the cases and the sincere women were correctly classified in 86 percent.

In the *Preliminary Longitudinal Phase,* 21 subjects have begun testing in two diagnostic categories, either herniated discs or acute local low back pain.

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XI. Orthotics

[212] COMPLIANCE MONITOR TO MEASURE PATIENT WEARING TIME FOR SPINAL ORTHOSES

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PURPOSE—Spinal orthoses play an important role in the treatment of spinal injuries, low back pain, and spinal deformities. Whether or not a patient complies with the prescribed wearing hours is considered to greatly influence the clinical outcome of orthotic treatment. At the present time, a reliable and objective method of measuring orthosis wearing time is lacking. Current estimates are based on self-reported compliance and estimated wear and tear of the orthosis itself. As a result, there are no objective data to evaluate whether a correlation exists between the orthosis wearing time and outcome of treatment for a given disorder. Further, there is no rational basis to determine the minimum number of wearing hours necessary to achieve good outcome for a given condition and type of orthosis.

In the proposed study we intend to refine the existing design of the compliance monitor that has been developed in our laboratory, and assess its accuracy and reliability in measuring wearing time for spinal orthoses under a variety of clinically relevant conditions.

METHODOLOGY—The study will be carried out in four stages. In the first, we will refine the existing design of the compliance monitor that has been developed in our laboratory, paying particular attention to the design of the data recorder unit and software. Next, we will assess the effects of temperature, humidity, and wear duration on the accuracy and reliability of the refined compliance monitor in the laboratory over a period of up to 3 mo, precisely controlling the temperature and humidity conditions with the use of an environmental chamber and the number of hours an orthosis is worn per day. We will test the instrumented orthoses on plaster casts under four environmental conditions and five wearing durations. In the third stage, we will validate the ability of the compliance monitor to make accurate measurements of orthosis wearing time during activities of daily (ADL) living using volunteer subjects. In the proposed study, 10 volunteers will be tested over a 1-wk period, with up to 23 hrs/day of orthosis wear time. Finally, we will evaluate the effect of long-term exposure to ADL on the durability and accuracy of the compliance monitor on 20 subjects for up to 3 mo, thus providing long-term data on the performance of the device.

PROGRESS—The software for the compliance monitor, transfer module, and host computer has been developed and tested. The new compliance monitor prototype as well as the new design of the transfer module underwent final testing, and 10 monitors were fabricated. Environmental chambers were designed and fabricated. Testing of an environmental chamber is underway. Testing for 10 volunteers is complete and data analysis is ongoing. The compliance monitor failed for three of the subjects, prompting a review of the software. One monitor failed due to programmer error, one failed due to a sensor wire interfering with a battery contact, and the third failed for unknown reasons. Investigation of the third failure is ongoing.

FUTURE PLANS/IMPLICATIONS—Subjects are currently being recruited for the final phase of the study, in which 10 will be prescribed part-time wear and 10 full-time wear. Availability of an accurate and reliable compliance monitor will allow clinicians to objectively study the relationship between compliance and outcome of orthotic treatment, and arrive at rational guidelines for prescribing orthosis wearing hours.

[213] ORTHOTICS DESIGN WITH ADVANCED MATERIALS AND METHODS: A PILOT STUDY

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PURPOSE—While the Spiral Orthosis (SO)—intended not only to stabilize a totally flaccid ankle joint in all directions, but also to simulate all lost musculature below the knee in all phases of the gait cycle—was conceived and clinically applied decades ago, continual materials problems have kept this potentially widely applicable orthosis out of the orthotics mainstream. The focus at present is to resolve these materials problems; then it is intended to see that the orthosis takes its rightful place in that broad range between posterior leaf spring and solid ankle orthosis types.

METHODOLOGY—The SO consists essentially of a flat strip of semi-rigid material that is wound about the limb in spiral form, beginning at the bottom of the foot, extending medially, then about the Achilles tendon, continuing around the shank and terminating at the medial tibial flare, where it is locked into place with a calf band having a triangular cross-section transversely. This forms an exoskeleton that is believed to conform to the numerous articulations of the endoskeleton of the natural foot/ankle/shank complex, in that no appreciable movement of the orthosis relative to the limb is apparent during ambulation.

As the orthotic exoskeleton simulates the endoskeleton, all surrounding musculature—plantar/dorsi flexors, inverters/everters—is simulated by the continual loading and unloading of the orthosis during the gait cycle. Nevertheless, the device is by no means a panacea. It would not be preferred where there is excess spasticity and/or swelling, nor where more rigid support is required, nor where, for instance, the plantar flexors are normal.

PROGRESS—Since solid polypropylene has proven unbreakable for the SO application in clinical trials, the focus has been to ameliorate the poor workability of the material. When an SO ''blank'' (the orthosis in flat form) is heated sufficiently for moulding about the cast of a patient's limb, it must somehow be transferred from the oven and held to the positive cast with sufficient pressure for accurate conformance. Generally, the necessary degree of softness is inconsistent with transfer and holding forces, often resulting in thinned, weakened regions. Such hit-or-miss construction is not conducive to broad application.

To minimize this problem, the first intention was to cold form several layers of polypropylene cloth on the positive cast, then fuse the layers with heat. It was found, however, that no matter how securely the material was restrained, it underwent pronounced shrinkage. Although this approach proved unviable, it clearly demonstrated that stock polypropylene cloth is prestressed as a manufacturing byproduct.

A new line of experiments led to layups consisting of both solid and cloth polypropylene constituents that offset the tendency of cloth shrinkage, so that the entire composite becomes prestressed, and thereby able to resist the external forces required to work the material by the orthotist.

PRELIMINARY RESULTS—Since virtually the only material polypropylene will firmly bond to chemically is itself, the fused layups of solid and cloth polypropylene should effectively be a single piece of material not subject to delamination, either due to reheating by the orthotist during SO construction or to stress during ambulation. This, at any rate, is the working hypothesis.

To examine this hypothesis one subject with bilateral ankle deficit was fitted. On one limb a composite polypropylene SO as described was fitted to one limb, and an acrylic SO was fitted to the other for purposes of comparison, in that acrylic does not have the known high fatigue resistance of polypropylene.

Reportedly, the subject preferred the added support provided by the composite polypropylene, which was not surprising since the blank was laid up particularly for this rather heavy person, while the acrylic was from available stock.

Notably, composite polypropylene is stiffer per unit thickness than stock solid polypropylene. And stiffness can be adjusted by the number of cloth layers used and by employing the thickness adjustability of the mould employed during fusion of the composite blank.

FUTURE PLANS—Means must be found to improve the surface finish of SOs made from the polypropylene composite. Also workability needs improvement regarding the tendency of polypropylene to adhere when heated; since standard release agents can be discouraging, experiments are ongoing with various wrappings on the SO blank. When the materials questions have been resolved, it remains to integrate the SO into the orthotics mainstream.

[214] COMPUTER-AIDED DESIGN AND COMPUTER-AIDED MANUFACTURING OF ORTHOPEDIC FOOTWEAR

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PURPOSE—The objective of this project is to develop a computer-aided design and computer-aided manufacturing (CAD/CAM) system to effectively and efficiently design and manufacture well-fitting, comfortable, and functional custom orthopedic footwear for US veteran pedorthic patients.

METHODOLOGY—To achieve this objective, the following research protocol has been established:

1. For a representative sample of the pedorthic patients served by the NY VAMC National Footwear Center (NFC), compile a computerized database of medical/podiatric/pedorthic conditions and footwear prescriptions, collecting 3-D digitized scans of the custom orthopedic lasts made, of the stock library lasts from which they were modified, and (when available) of the foot casts, together with 2-D digitized scans of the associated upper patterns for the orthopedic shoes made;
2. Analyze the data compiled to establish and quantify VA NFC orthopedic footwear design and manufacturing requirements;
3. Develop an intuitive, user-friendly, clinically effective and efficient pedorthic CAD/CAM system meeting those requirements;
4. Conduct limited clinical testing of the pedorthic CAD/CAM system developed to identify those areas/features that are successful and those that require further research and development.

PROGRESS—From the VA NFC pedorthic patient population, 289 subjects were sampled, their pertinent medical/podiatric/pedorthic information recorded, and their shoe lasts, the stock library lasts, and the upper patterns optically digitized and compiled in the project database. These data were analyzed to establish the range of medical/podiatric/pedorthic conditions and the respective footwear prescriptions, together with statistical averages and standard deviations for the last/footwear types and modifications used in treatment thereof. From the data compiled, specifications for a VA NFC pedorthic CAD/CAM system were established and a pedorthic CAD/CAM system developed.

Previous work on development of a pedorthic CAD system fulfilling these requirements was revised. Efforts were concentrated on development of an advanced dual monitor system based on the WindowsNT platform, capable of simultaneous display of multiple views and different perspectives for ease of model visualization, evaluation, and modification. The system was augmented so that either an optically digitized scan of a patient's foot, or a set of VA-prescribed pedal measurements can be used as the system input. The input scan/measurements are used to automatically grade a style and model of last selected by the user to obtain the best fit possible from the system's predigitized, orthopedic last library. The system was expanded with digitization and storage of eight new orthopedic models in the system last library.

In addition to the usual CAD system design features, this system has design template and modification region linking to multiple landmarks with automatic regional scaling. It also has last feature and regional boundary identification and registration; variable reference center selection and realignment ability, including forefoot abduction and adduction; advanced spline model surface smoothing; menu selection for ease in application of common regional modifications (toe box expansion, bunion relief, metatarsal pad, scaphoid pad, medial and/or lateral wedges, etc.); input of Tekscan F-Scan (or equivalent system) pedal plantar stress measurements for last plantar surface and shoe insole design; uniform and variable plantar sole thickness selection for elevation control for leg length discrepancy compensation; etc. In addition, definitive 3-D last to 2-D shell flattening capabilities were incorporated, together with shoe upper pattern selection from the system library with automatic grading, piece definition, and design modification and styling capabilities.

CAM toolpath correction, clearance, and surface smoothing software for last manufacture was also written and tested, and the CAM milling machine was upgraded to permit carving of CAD lasts in high density polyethylene. Clinical trials with 4 control subjects and 10 pedorthic patients have been successfully conducted to date using this system.

FUTURE PLANS—Refinement and enhancement of the system shall continue. The results and the knowledge obtained in this project, together with results obtained by the investigators in their other research in tissue biomechanical characterization, measurement of static and dynamic loading, and foot/ankle biomechanics, shall be utilized to develop new, improved, biomechanically based orthopedic footwear designs.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[215] CLINICAL TRIAL OF FOOTWEAR IN PATIENTS WITH DIABETES

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PURPOSE—Lower limb ulcers precede about 85 percent of diabetic amputations. Nearly half of the events that begin the causal pathway leading to ulcers and amputation are footwear related. Yet the efficiency of footwear in preventing ulcers and amputations in the high-risk diabetic population has received limited experimental investigation. Randomized trials have not assessed the combined contribution of therapeutic shoes and different types of insoles on foot ulcer prevention while also addressing patient footwear adherence.

This study is designed to determine the extent to which study shoes and study insoles will reduce incidence of reulceration in diabetic individuals with a prior history of foot ulcer, and to estimate costs of ulcer prevention using these strategies.

METHODOLOGY—Diabetic patients with a prior healed foot ulcer are being randomized to study shoes and insoles or their own footwear. Patients will be followed for 2 yrs to determine the incidence of reulceration.

PROGRESS—Patients are currently being recruited and randomized to the trial.

FUTURE PLANS—We shall continue enrollment, data collection, and monitoring. This trial will assess the potential for savings in morbidity and provide information on potential cost savings that could be achieved in the VA with footwear interventions.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[216] THE ROLE OF ORTHOTIC INTERVENTION IN RESOLUTION OF PLANTAR FASCIITIS

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Sponsor: *Department of the Army; Post Polio Clinic of the Albert Einstein Healthcare Network*

PURPOSE—A major goal is to determine the effect of short leg braces and shoe inserts on the pattern of muscle use and resolution of symptoms in individuals with plantar fasciitis. In addition, it is desired to determine whether the change in muscle use patterns may be indicative of resolution of the overuse symptoms. This may facilitate inferences on effective treatment options.

METHODOLOGY—Subjects from two groups with clinically documented plantar fasciitis have completed the protocol to date. Group 1 are subjects with Post Polio Syndrome (PPS) and Group 2 are controls with no known neurological, orthopaedic, or other disorders which may affect muscle use patterns during gait. Each subject is fitted with a custom orthotic (short leg MAFO for the PPS subjects, in-shoe orthotic for the controls). Plantar fasciitis symptom severity is recorded using a visual analog scale at the initial visit. After 1 wk of orthotic use, subjects are evaluated in the Gait Lab. EMG of soleus, tibialis anterior, quadriceps, and the biceps femoris of the hamstrings group are recorded, as are motion and joint moments of the lower limbs and walking speed. The above data are recorded both with and without the orthosis; order of testing is randomized. At the final visit, approximately 1 mo later, the severity of the plantar fasciitis symptoms is again recorded.

PROGRESS—This is the first year of the study; testing is ongoing, and 20 subjects have been seen to date. Data analysis is being undertaken to determine trends.

PRELIMINARY RESULTS—Differences have been found in kinematic data as well as in EMG recordings in conditions when walking with the orthosis as compared to walking without the orthosis. Ensemble averaged kinematic profiles and EMG profiles clearly indicate differences in patterns with and without the orthosis. An insufficient amount of data has been analyzed so far to be able to speculate about correlation between resolution of symptoms and changes in muscle use patterns as well as in trends in the methods of compensation.

FUTURE PLANS—It is desired to test an additional 20 subjects to establish a sample large enough for statistical significance. Trends in how gait parameters are affected in the PPS population as compared to the controls will also be analyzed. In general, trends in compensation to the orthosis will also be monitored as part of an ongoing effort to document and model compensation mechanisms.

[217] MEDICAL EVALUATION OF 70 PARAPLEGICS USING A PRACTICAL FES WALKING ORTHOSIS

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PURPOSE—The objective of this evaluation research was to determine whether a well-designed hybrid system based on mechanical and electrical muscle stimulation principles can be applied to the majority of the paraplegics applying for rehabilitation of walking functions; whether such a walking system can be successfully accepted by a large number of patients; and whether persons who accept such an orthosis and use it regularly can receive significant health benefits.

METHODOLOGY—Seventy persons aged 18 to 65, with paraplegia ranging in injury level from C-5/6 to T-12, with a wide range of spasticity and contractures of the leg muscles and joints, were accepted to the program and fitted with the Louisiana State University (LSU) Reciprocating Gait Orthosis (RGO), powered with a portable electrical stimulator to activate the leg muscles. Patients were trained to stand up, walk at least 180 m, walk on grass, ramps, and curbs, and to sit down as well as don and doff the orthosis. Blood, urine, echocardiogram, and spasticity tests were given to each subject at the beginning and end of the program.

RESULTS—It was shown that 75.7 percent of the subjects could successfully use the orthosis without requiring any assistance from others for the prescribed tasks. The medical tests demonstrated that with the minimal use of the walking orthosis for 3 hrs a week, a significant reduction of cholesterol, spasticity hydroxyproline, and calcium was noticed, together with improvements in heart and lung functions.

IMPLICATIONS—The LSU-RGO, powered with muscle stimulation, demonstrated that it is a practical walking orthosis for persons with paraplegia, being accepted by 76 percent of the subjects while improving bone, ligament, and cartilage conditions, together with reducing spasticity and cholesterol. Improvement in heart and lung functions further assert the benefit of using such orthosis.

RECENT PUBLICATIONS FROM THIS RESEARCH

Reciprocating gait orthosis powered with electrical muscle stimulation (RGO II): Part I. performance evaluation of 70 paraplegics. Solomonow M, Aguilar E, Reisin E, et al. Orthopedics 1997:20:315–24.

Reciprocating gait orthosis powered with electrical muscle stimulation (RGO II): Part II. performance evaluation of 70 paraplegics. Solomonow M, Aguilar E, Reisin E, et al. Orthopedics 1997:20:411–8.

[218] CRUTCH AMBULATION

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PURPOSE—Crutch ambulation is extremely inefficient compared to normal upright bipedal locomotion. Crutch users are slow and take small steps. Even at this slow velocity, ground reaction forces are higher than for normal walking. Models of human ambulation have been proposed in which walking is described as a passive process (i.e., a system that requires no energy input). Many of these models are based on the inverted pendulum, with the idea that energy is transferred back and forth between its kinetic and potential forms during the gait cycle. Physical models have also been built that can walk with little energy input. By taking advantage of the inverted pendulum and rocker-shaped feet, the model can roll with little effort. These models are very similar in appearance to swing-through crutch ambulation. Both have four legs, with the inner two coupled and the outer two coupled. Also like the model, the crutches (and often immobilized legs) are passive systems.

METHODOLOGY—Crutches are not often used, because with the current designs energy costs are much higher than for normal walking or wheelchair locomotion. It is hypothesized that crutch ambulation can be improved and made easier through the application and expansion of what is currently known about bipedal locomotion. Since passive bipedal devices can be built, there do not appear to be any mechanical reasons why crutch ambulation efficiency cannot be increased, by new crutch design concepts, training, and new locomotion techniques.

PROGRESS—Initial data have been collected using a prototype of a modified crutch design based on passive dynamic walking machine models. Rockers were added to the terminal end of elbow crutches and to ankle-foot orthoses. One subject was used for the initial testing. Three-dimensional kinematic data and force plate data was collected for trials of swing-through gait using normal crutches and modified rocker crutches. Normal walking trials were also collected.

RESULTS—Comparison between the data of normal ambulation and swing-through crutch gait with standard crutches shows that there is considerable room for improvement. The most obvious variations were the reduced speed, the increase in the peak vertical ground reaction force, and the large fluctuations in the horizontal forward velocity. As a general observation, none of the curves associated with crutch ambulation had the smooth symmetric patterns typical of normal ambulation. The modified crutches did positively alter ambulation parameters; for example, timing was more symmetric between the body and crutch stance.

FUTURE PLANS—Analytical models are being developed to investigate swing-through crutch ambulation. These models will address parameter variation including characteristics of the rocker radius and position and addition of compliant spring mechanisms for shock absorption and energy storage. Unlike the previous models in which the inner and outer leg couples are identical, the size and mass distribution of the crutches (outer) and body (inner) for the crutch user are not symmetric; therefore, the model will also be used to assess the use of asymmetric parameter selection for each link couple. The results of the model are expected to improve the speed and reduce the large fluctuations in the velocity as well as the large peak vertical ground reaction forces and thereby improve the efficiency of swing-through crutch gait.

RECENT PUBLICATIONS FROM THIS RESEARCH

In search of better crutches. Miller LA. In Motion Mag 1997;7(3):30–2.

[219] MEASUREMENT OF PLANTAR FOOT SOFT TISSUE PROPERTIES OF PERSONS WITH DIABETIC NEUROPATHY FOR PREDICTION OF PLANTAR FOOT PRESSURES AND ASSESSMENT OF PLANTAR ULCERATION RISK

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PURPOSE—For people who suffer from diabetes, especially those complicated by neuropathy, foot problems can be a common phenomenon. One of the more common is plantar ulceration that can range from small superficial ulcers to deep penetrating ulcers with bony involvement. A common occurrence and necessary prerequisite for ulceration is elevated plantar pressure. Investigators as well have shown correlations between ulcer formations and sites of high pressure and/or loading. Shoe orthotics have been shown to be effective in the reduction of pressures. A new type of orthotic involves a plastic insole filled with silicone gel. Our goal has been to test this orthosis for its effectiveness in reducing plantar pressure.

METHODOLOGY—An important issue in dealing with the experimental determination of pressure distribution between the foot and an orthosis is that the pressure measuring mat introduces another layer under the sole, which in itself may modify the pressure distribution. Therefore, we carried out tests with and without shoes. Further to this approach, current research also targets increasing our understanding of the effectiveness of experimental techniques in these types of investigations by modeling the plantar soft tissues and being able to predict pressure distributions from soft tissue geometry and mechanical properties.

PROGRESS—A viscoelastic sphere model with realistic properties, which can be used to represent the plantar surface of the foot during locomotion, was developed. The mechanical properties of the sphere were identified using experimental data on heel pads. To validate the model, the results of the experimental study were reproduced by simulating the impact tests. Sensitivity analyses of the model parameters were carried out. The model was found to be insensitive to variations both in stiffness and damping properties. The change in the thickness of the soft tissue, however, affected the maximum force of deformation, proportionally. A symmetrical pressure distribution for the sphere during impact was calculated. It was concluded that this device can be incorporated into a model representing the plantar surface of the foot.

RESULTS—The modeling approach presented here is not limited by the utilization of spherical bodies: the same approach can be applied to any irregularly shaped surface as long as the geometry of the soft tissue is available in some form. This will allow for higher models, using multiple overlapping spheres, to create a complex geometry, such as a more physiological model of the foot.

FUTURE PLANS—We intend to investigate a more physiological model of the foot for application in the study of the diabetic foot: using a similar approach, recreating the geometry of bones and tissues for calculating the maximum applied forces and pressure distribution under the foot. This is even more attractive, considering the possibility of adding the effect of shoe insole as another spring-damper system in series with the foot model to be able to compare the model results with previously acquired patient data and eventually give some indication about the mechanics of foot ulceration in persons with diabetes.

[220] ORTHOTICS FOR MYELOMENINGOCELE PATIENTS, TEENAGE VERSUS CHILDHOOD

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PURPOSE—The purpose of this research is to determine the optimum orthotic system for the myelomeningocele (MMC) child and its carry-over to teenagers. There are three specific goals of this research: 1) to delineate the differences in gait requirements and performance of pediatric versus teenage patients. 2) to compare the available strengths and range of motion of the two subject groups. 3) to differentiate orthotic forces, foot stability, and biomechanics of two knee-ankle-foot orthoses (KAFOs) and three ankle-foot orthoses (AFOs).

METHODOLOGY—Children (4–7 years) and teenagers (12–17 years) with MMC lesions (lumbar or sacral functional levels) who rely on KAFOs or AFOs to walk will be recruited as subjects. Individuals using a KAFO will be randomly tested with standard and supracondylar orthoses. Individuals using an AFO will be randomly tested with three AFO designs: 1) solid polypropylene posterior shell, 2) posterior entry anterior shell (floor-reaction), and 3) dorsiflexion restraining articulating orthosis (Rancho design). Subjects will wear each brace for a minimum of 1 mo prior to testing.

PROGRESS—EMED insole pressures have been collected for 10 controls (5 children, 5 teens) to establish a normal database of foot pressures. Currently, 11 subjects (4 children, 7 teens) have been admitted into the study and 6 have completed all testing.

RESULTS—Subject characteristics for one teen (S1) and one child (S2) who use AFOs are described. Both subjects are community ambulators who are able to walk without assistive devices. Stride characteristics for both subjects reflect velocity greatest for the anterior shell, slowest for the posterior shell. For both subjects, the greater velocity achieved during ambulation in the anterior shell brace was the result of increases in both stride length and cadence in comparison to the posterior and articulating braces.

All three braces are designed to control ankle dorsiflexion (DF) in terminal stance, allowing the user to achieve heel off and a subsequent increase in stride length. For both subjects, peak DF in terminal stance was greater than normal for all 3 braces. Additionally, peak DF was delayed by 3 to 8 percent of the gait cycle (GC) in each of these AFOs. The least restraint of stance DF occurred with the articulating brace design. For S1, the posterior shell brace provided the greatest restraint of DF; however, a corresponding earlier heel off and increased stride length was not recorded. For S2, the anterior shell best limited DF and resulted in only a slightly delayed heel off (38 percent GC vs. 30 percent normal). For both subjects, the anterior shell brace provided the earliest peak dorsiflexion (S1 at 50 percent GC; S2 at 49 percent GC) and resulted in the longest stride length of the three braces.

Knee motion was similar in strategy across braces for the two subjects, but different between subjects. S1 tended to have excessive knee extension throughout the stance phase, exhibiting a period of instability in loading response, characterized by extension followed by flexion. S2 tended to exhibit excessive knee flexion throughout stance. The knee control strategies selected by these subjects may be a result of the proprioceptive and/or strength deficits of the individuals.

Moment data revealed a delayed peak PF moment for all braces in S1, for the posterior shell only in S2. However, the period during which a PF moment occurs (initial contact through 14 percent GC in controls) is delayed most for the posterior shell in both subjects, slightly delayed for the anterior shell in S1 only. At the knee, however, peak knee moment during loading response is reduced from normal in all braces for both subjects, an indication that the strategy of both subjects at the knee is to reduce the quadriceps demand. S1 achieves this by extending the knee prior to loading, and S2 by contacting with the knee already flexed.

Energy cost data revealed that the rate of O_2 use was similar for all braces for both subjects at 5 min of a

20-min walk. S1 showed an increase in the rate of O_2 use after 10 min in all braces, which was not seen with S2. In fact, S1 was unable to walk more than 10 min, while S2 completed the 20-min collection period. For all six of the tested subjects, only S2 was able to walk the full duration.

FUTURE PLANS—Recruitment and testing of subjects will continue. Data analysis of the normative foot pressure data will proceed for publication and dissemination. From the data obtained in this study, a biomechanical model will be conceived to guide the design of more optimal orthoses to facilitate the ability to walk and to provide long-term foot protection.

[221] DEVELOPMENT OF LOWER EXTREMITY ORTHOTICS FOR CHILDREN WITH MYELOMENINGOCELE

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PURPOSE—The aim of this project is to design improved bracing for the person with myelomeningocele. Orthotic support for this population has always been difficult, but it is important for the physiological and social development of the child. Target goals for the new KAFO and AFO designs include stronger, lighter AFO shells with improved ankle joints and development of improved KAFO braces with easily operated knee joints.

PROGRESS—A number of simple leaf-spring type AFOs have been fabricated, as proof of concept, from pre-impregnated carbon fiber (pre-preg) cloth. The use of composite pre-preg permits a strong and lightweight AFO to be custom-manufactured from a cast mold. The pre-preg cloth is applied over the cast and then heat cured, under vacuum, in a common fabrication oven.

A modification of the standard curing process of the composite has the potential to advance the overall fitting and fabrication process as well as the design of the brace itself. It was found that by partially curing the composite part while it is draped over the production mold, the material would, after removal and cooling, hold its laminated integrity while allowing the orthotist to hand-modify it to the patient. The part is then returned to the oven for final cure. This advance in process may allow the manufacture of modular shaped and sized AFOs to be distributed to orthotists in the partially cured state, with no need for cold storage or special handling. They can then be custom shaped by hand to the patient. This material is also heat postformable with common orthotic tools. These advances eliminate some of the traditional problems of composite AFO manufacture, including the noxious (sometimes toxic) smell released during production, the difficulty in modification for patient fit at delivery, and adjustment for later changes as needed.

In the KAFO design project, successful fabrication of a prototype cantilever (single upright) KAFO has been accomplished. It is a single-upright design with smooth, flowing curves for enhanced strength and cosmesis. To complete the orthosis, an orthosis-to-patient interface of molded polypropylene was drape-vacuum molded, and Velcro straps were attached to the thermoplastic. A rugged Teflon-coated aluminum bearing appears suitable for the single-axis knee joint. This bearing was epoxied into place between the carbon fiber layers of the proximal part, and a clevis overlap was designed into the distal part.

FUTURE PLANS—The new pre-preg material will be used to laminate several AFOs for mechanical testing and, ultimately, evaluation with human subjects. Following an investigation of the failure modes of the material, with attention to the possibility of injury from sharp fracture edges, a safe design will be tested on team member controls prior to an in-clinic evaluation. A suitable interface between the carbon fiber and wearer, such as a liner material, will be developed as needed. Alternative composite AFO designs will be evaluated including anterior or posterior open-calf sections. The new partial cure process will be further investigated.

The aim will be to explore design variations to best exploit the new material and fitting process. Comparison with conventional polypropylene AFOs will be made in terms of wearer comfort, gait performance, brace weight, bulk and cost.

[222] MOBILE ARM SUPPORTS FOR CHILDREN

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PURPOSE—Mobile arm supports (MAS) are wheelchair-mounted mechanical linkages designed to support the weight of the arm and provide assistance to shoulder and arm motions. They have improved the function and independence of many individuals with flaccid paralysis or paresis of the shoulder and elbow flexor muscles. Problems with commercially available designs have limited their use in spite of their low cost and functional benefits. Drawbacks include complexity of the set-up and adjustment procedures, poor cosmesis, link interference, and doorway clearance. This project aims to improve MAS design to address these deficiencies.

PROGRESS—A survey of MAS users has been conducted to establish design goals. The results, combined with direct observations of users and input from experienced clinicians, provided valuable input to and stimulus for establishing design specifications. Design goals have been formulated emphasizing ease of adjustment, low profile, and attractive cosmesis along with the requisite ease of motion.

A multi-link articulated arm for the MAS has been developed and shows promise. It protrudes less and is more flexible in configuration, so it offers less interference to passage through door frames and around tables. Several prototype wheelchair mounts to facilitate arm balance adjustment have been designed and are under evaluation.

Clinical trials of the new mobile arm support began in early 1997. To date, 12 persons, mostly children, have tried the device. A User Group of 10–12 children is being formed to work with the project team throughout the developmental phase. This will enable prompt testing of various design features and quick feedback from a knowledgeable group of children and their parents.

RESULTS—The survey of MAS users documented that over half the respondents acknowledge a benefit from their MAS and continue to use it for a variety of activities, including eating, typing, playing games, and simple arm exercise. Seven users employ the device to help pilot their power wheelchairs. This result was a surprise since it was assumed that the mobility of the arm in the support might pose stability problems for joystick control. Complaints included difficulty in adjusting and maintaining the MAS balance alignment, device bulk (especially in clearing doorways), and poor appearance.

User trials of the new MAS and mounts are providing valuable insight into both benefits and drawbacks of the design. Link geometry and segment lengths are important factors in allowing both full range of motion and avoiding interference with the pivoting trough that supports the forearm. Appropriate bearing selection is crucial in providing low-friction motion while maintaining reasonable cost. The enhanced cosmesis is appreciated. Industry has expressed interest in producing an improved MAS, and therapists outside Rancho have indicated a desire to try it when it becomes available.

FUTURE PLANS—A new mounting system will be selected from among several candidates. The design must prove itself satisfactory for a number of clinicians and MAS setups, and provide easy attachment to the wheelchair and quick adjustment of the MAS. Expanded clinical trials of both the mount and the entire new MAS system will then be initiated. The ability to quickly relocate the MAS from the wheelchair to a pre-adjusted mount on a desk or table will be investigated as a useful option. Improved performance must not come at too high a price, so design for low-cost manufacture of all components will remain a priority.

[223] POWERED ARM ORTHOSIS

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PURPOSE—A powered arm orthosis was developed to aid those who suffer from muscular dystrophy. The purpose of the device was to provide the user with a powered, controlled arm movement that required minimum muscle exertion to counteract gravity. Specific goals were to enable the user to independently perform tasks such as grooming and feeding.

METHODOLOGY—The orthosis is designed to mount on an electric wheelchair and provides two powered degrees of freedom: shoulder rotation in the sagittal plane, and elbow flexion/extension. Passive shoulder rotation about the vertical axis is also provided. The powered movements are controlled by two toggle switches activated by the opposing hand. The orthosis uses chain drives and is powered by two 12 VDC motors mounted on the back of the wheelchair.

RESULTS—The device was tested by three nondisabled volunteers and was successfully operated to provide the desired grooming and feeding functions. Elbow flexion was independently controlled. However, shoulder rotation simultaneously caused a small amount of elbow flexion to occur.

FUTURE PLANS/IMPLICATIONS—The prototype powered arm orthosis successfully demonstrated the feasibility of a wheelchair-mounted design. A second generation prototype, powered by two hydraulic cylinders, is currently under construction. This new design will completely uncouple shoulder rotation from elbow flexion.

[224] LOGIC-CONTROLLED ELECTROMECHANICAL FREE-KNEE ORTHOSIS

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PURPOSE—This project addresses the problem of restoring lower limb function to persons who require the use of a knee-ankle-foot orthosis (KAFO) for ambulation and must have the knee locked for stability during gait. Currently, these persons are usually fitted with either a conventional KAFO that has a knee joint equipped with a manual mechanical lock, or with a free-knee orthosis equipped with an eccentric knee joint. These orthotic schemes result in a lack of knee movement during the swing phase of gait, producing inefficient gait. The goal of this project is to design, develop, and test a small, lightweight, electronically controlled knee joint that can be installed on a conventional KAFO. The knee joint will unlock during the swing phase of gait and lock during the stance phase of gait.

METHODOLOGY—This new orthotic system is composed of two major parts: mechanical hardware and an electronic control system. The mechanical hardware consists of a standard polypropylene orthosis, a mechanical clutch, and a solenoid to release the clutch when required. The electronic control system consists of sensors which go in the shoe of the subject to sense the position of the foot. When the foot is on the ground, a logic circuit keeps the clutch locked. When the foot is in the air, the same logic circuit unlocks the clutch and lets the knee swing freely.

PROGRESS—This research project has developed a new design which can be adapted to an existing KAFO. This system has been successfully tested on four subjects with paralysis of the lower limb. Dynamic gait analysis has shown improvements in the knee motion pattern while using the new KAFO. The knee swing-phase motion pattern approaches the motion of a nonimpaired individual. The improvement in knee motion during swing was effective in lowering the energy required for walking. Energy consumption measurements were obtained on level ground and on a slope with a 5 percent incline. The oxygen consumption rate and energy costs were significantly lower when the swing phase knee motion was unrestricted during gait.

FUTURE PLANS—This research will be continued in the future. Plans are to miniaturize the electronics and integrate all elements into the orthosis.

IMPLICATIONS—Surveys show that rejection rates for KAFOs range from 60 to nearly 100 percent. This high rejection rate is due to the increased energy requirements for locomotion when using conventional KAFOs. The newly proposed orthosis design which allows free knee motion during the swing phase of gait requires less energy to walk. It is anticipated that this improvement in walking efficiency will lead to an increased acceptance rate by those who require a KAFO for morbidity.

RECENT PUBLICATIONS FROM THIS RESEARCH

A digital logic controlled electromechanical long leg brace. Irby SE, Kaufman KR, Sutherland DH. Proceedings of the 15th Southern Biomedical Engineering Conference; 1996 Mar 29-31, Dayton, OH; 1996.

Energy efficient knee-ankle-foot orthosis. Kaufman KR, Irby SE, Mathewson JW, Wirta RW, Sutherland DH. J Prosthet Orthot 1996;8(3):79–85.

[225] DETERMINATION OF THE EFFECT OF RANGE OF MOTION CHANGES IN AN ARTICULATED ANKLE FOOT ORTHOSIS ON LOWER LIMB MUSCLE DEMANDS

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PURPOSE—Progress in a continuing project to utilize EMG signals to assist in the orthotic alignment procedure has been made. Changes in muscle demands due to minor modifications to the range of motion (ROM) in an articulated ankle foot orthosis have been measured in a Post Polio Syndrome (PPS) population. Initial work showed that statistical analysis of integrated linear enveloped stride EMG signals from differing test conditions allowed comparison of muscle activity corresponding to these conditions. The initial and post-accommodation responses to new alignment conditions were assessed.

METHODOLOGY—Subjects walked in their own orthotics in several different ROM restrictions. Surface EMG signals from tibialis anterior, soleus, rectus femoris, vastus medialis, vastus lateralis, and the long head of biceps femoris were recorded. Data were collected immediately after administering the change in ROM to the orthosis and again after the subjects had used the orthosis in one of the new alignments for a period of one to several months. Linear enveloped and integrated stride EMG data from different conditions were statistically compared. Ensemble averaged profiles were also visually checked to eliminate spurious statistical significance.

PROGRESS—Additional PPS subjects have been evaluated to assess whether neuromuscular deficiencies affect the trends found in controls. For these subjects, heart rate, joint moments, and brace preferences were measured to corroborate statistical findings from EMG.

PRELIMINARY RESULTS—Muscle response was well defined and consistent in the PPS subjects. The processing method used facilitated the statistical comparison which showed significant changes between test conditions. Statistical comparison of ensemble-averaged EMG profiles indicated differences which were not readily obvious through the more clinically prevalent visual analysis. Furthermore, some common clinical heuristics, such as increasing ankle plantarflexion to relieve knee extensor muscles, were found to not always hold true. Although joint moment date was incomplete since subjects were not asked to target force plates, there was a modest correlation between the moment and EMG data. Trends in the EMG data suggested that the initial response to any new condition may be an extreme one, where there was either maximal or minimal muscle activity.

FUTURE PLANS—Testing of additional subjects and developing a musculoskeletal model to predict the effect of orthotic ROM constraints on muscle demands are pending.

XII. Psychological and Psychosocial Disorders

[226] REHABILITATION EFFECTS OF PAY, ACTIVITY, AND SUPPORT INTENSITY ON SCHIZOPHRENIA

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PURPOSE—This research investigates the benefits of productive activity in the rehabilitation of patients with schizophrenia. Key questions are: 1) does pay increase participation in work activity and lead to higher rates of work placement in the community? 2) do higher intensity services yield better clinical outcomes than standard services? 3) is greater productivity associated with better clinical outcomes? and 4) is performance on psychological and neuropsychological measures a useful predictor of rehabilitation outcomes?

METHODOLOGY—One hundred and twenty patients with DSM III-R confirmed diagnoses of schizophrenia and schizoaffective disorder are being recruited from the general psychiatric service and stratified by prior work function. Subjects are randomly assigned to one of two levels of pay: $3.40 per/hour up to 20 hrs weekly or no remuneration; and one of two levels of support, standard or high. High support subjects have access to a job coach, attend a weekly group meeting where vocational issues are addressed, and are provided biweekly work performance feedback. All subjects are offered 6-month work placements. Research staff perform biweekly evaluations of job performance using the Work Behavior Inventory (WBI), symptom levels using the Positive and Negative Syndrome Scale (PANSS), and quality of life (QOL). Subjects are evaluated at baseline, 5 mo, 1 yr, and follow-up on demographic, neuro-behavioral and productivity variables.

PROGRESS—We have had over 115 referrals, of which 110 have completed all intake procedures and have been randomized into the study. This rate is slightly lower than planned, due almost exclusively to a change in the work group composition that necessitated a training period for the new members. However, we expect to recruit the planned 120 subjects about 2 mo behind schedule. Currently, 62 subjects have been assigned to the pay condition and 48 to the no pay condition; 55 to the standard support condition and 55 to the high support condition. Of the 110 subjects who have completed intake procedures, 83 have elected to continue to participate following randomization. As a group, these subjects have worked 15,649.75 hours, and we have performed 579 WBIs on them and conducted 122 weekly high support meetings. At 87 percent, attendance for group meetings has been excellent, and there has been surprisingly lively participation on the part of even the most withdrawn and symptomatic subjects. Also, we have conducted 642 weekly PANSS interviews, 329 QOL interviews, 520 group questionnaires, and 232 Job Satisfaction Inventories. In total we have conducted 1723 weekly assessments. Follow-up data are being gathered. 89 out of 95 subjects (94 percent) due for 5-mo follow-up have completed that procedure. Of those not completing it, two have died and four refused. Reevaluation of baseline measures for all subjects at 1 yr is concurrently being conducted. Of the 77 subjects in the program for 1 yr, 68 (89 percent) have completed the 1-yr follow-up battery.

RESULTS—With 85 percent of the total sample collected, we have not yet attempted to answer the primary questions outlined in the objectives section;

however, a preliminary look at the data shows subjects in the high support condition work approximately 12 percent more than those in the standard condition, and all of the paid participants had at least 1 wk of work while only 50 percent of the unpaid participants worked at least 1 wk. Other analysis include a validation study verifying the psychometric properties of the WBI and the Wisconsin Card Sorting Test. We also have completed several investigations on cognitive impairment in schizophrenia, including: 1) the identification through a taxometric analysis of a cognitively disorganized subtype of schizophrenia; 2) the relationship of cognitive impairment to insight in schizophrenia; 3) patterns of cognitive impairment in deficit and nondeficit forms of schizophrenia; and 4) the cognitive predictors of improved work performance over time in schizophrenia. We have also investigated the influence of personality variable of work performance.

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XIII. Sensory, Cognitive, and Communication Aids

A. Hearing Impairment

[227] COMPUTERIZED ADAPTIVE METHODS FOR SELECTING HEARING AIDS

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PURPOSE—The objectives of this project were to evaluate the relative merits of selected nonlinear signal processing strategies for use in hearing aid design and to explore the use of subjective judgments for measuring speech intelligibility and quality for application in hearing aid evaluations.

METHODOLOGY—The overall research plan for this area of study included the comparative assessment of three signal processing strategies: 1) linear amplification; 2) output compression (compression ratio 8:1, fast attack time); and 3) symmetrical peak clipping. Compression and clipping have been advocated for use in limiting the output of a hearing aid while linear amplification was used as a reference condition. A digital master hearing aid was developed and used to process the speech signals, set the compression and clipping parameters, and provide the prescribed frequency-gain response for groups of individuals with moderate-to-severe sensorineural hearing loss. Both speech intelligibility and speech quality performance for sentence material was used to assess the differences in perceptual performance among the experimental strategies. Stimuli were presented at sound pressure levels below and above the threshold for clipping and compression.

Although the assessment of subjective sound quality has been recognized as essential for determining patients satisfaction with a hearing aid, its measurement has received only modest systematic investigation and no clinical protocol has been widely accepted. In one experiment, subjective judgments of speech clarity and intelligibility were examined for both nonimpaired and hearing-impaired listeners using the psycho-physical methods of paired comparison and category ratings. In a second experiment, judgments of clarity and intelligibility were rated for several conditions in which frequency response and/or signal-to-noise ratio was varied while intelligibility was equated based on articulation index (AI) theory.

PROGRESS—The investigations revealed that speech intelligibility was only modestly affected by peak clipping or compression while listening in a quiet environment. Speech quality, however, became progressively poorer as speech was delivered at increasingly higher levels above the threshold for clipping. In backgrounds of noise, both intelligibility and quality were more adversely affected by peak clipping than by compression or linear amplification. The results from these experiments were presented at several scientific meetings cited later in the publication and presentation list. Currently we are completing analysis of the results and preparing it for publication.

RESULTS—These results indicated that the output of a hearing aid should be limited with compression rather than peak clipping. While assessing processing strategies in a digital master hearing aid can provide important comparative results for making decisions about the relative merits of various circuitry options, future investigations should also include clinical trials so that the comparative effects of peak clipping and output compression can be assessed in more naturalistic settings.

In the initial experiments on subjective sound quality, speech clarity judgments obtained by paired comparisons and category rating were highly related to the AI estimates both for control and hearing-impaired subjects. When the performance range was wide, both methods provided similar judgments for the control subjects. For the hearing-impaired subjects, paired comparisons were more sensitive than category rating. When the performance range was narrow, paired comparisons were more sensitive than category rating in differentiating between filters for both groups of subjects. This difference was less obvious for the controls when paired comparison data were converted to the category ratings. Large between-subject variability was evident for the hearing-impaired subjects on the psychophysical scaling procedures, most notably for category rating.

When judging the clarity among stimulus items where performance varied over a wide range, both category rating and paired comparisons provided comparable judgments for controls. For conditions in which perceptual differences between stimulus items were restricted either by the choice of conditions or by the effects of sensorineural hearing loss, the method of paired comparisons was the more sensitive procedure.

The purpose of the second investigation was to determine whether subjective judgments of clarity or intelligibility would be rated equally among conditions in which speech was equated for predicted intelligibility (using the Speech Intelligibility Index, SII) but varied in bandwidth. Twenty control listeners rated clarity and intelligibility for sentence material (Hearing In Noise Test) in speech-shaped noise at six paired-low and high-pass filtered conditions in which SII was equated for each pair. For three paired conditions, predicted intelligibility increased as SII was increased monotonically (0.3, 0.4, 0.5). In the remaining paired conditions, SII continued to increase monotonically (0.6, 0.7, 0.8) but predicted intelligibility was held at a maximal level (>95 percent). Predicted intelligibility was estimated from the transfer function relating SII to speech recognition scores determined in preliminary experiments. Differences in ratings between paired low- and high-pass filtered sentences did not reach statistical significance for either clarity or intelligibility, indicating that the spectral differences at equivalent SIIs did not influence the judgments for either of the two dimensions. For conditions in which predicted intelligibility increased, both clarity and intelligibility ratings increased in a similar manner. For conditions in which predicted intelligibility was maximized, intelligibility ratings remained the same statistically across conditions while clarity ratings changed modestly. Although high correlations were observed between clarity and intelligibility ratings, intelligibility ratings were consistently higher than clarity ratings for comparable conditions. The results suggested that controls produced clarity or intelligibility ratings for the same speech material and experimental conditions that were highly rated but differed in magnitude. Caution is required when substituting clarity for intelligibility.

IMPLICATIONS—Future investigations should be directed toward establishing the factors associated with sensorineural hearing loss which produce large between-subject variability and reduced sensitivity when using category ratings as compared to paired comparisons. Further consideration should be given to methods in which subjects make an assessment of a preferred condition or processing scheme based on a paired comparison paradigm which incorporates a rating scale to indicate the strength of their preference.

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[228] CHANGES IN AUDITORY ABILITIES WITH HEARING AID USE

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PURPOSE—Recent investigations suggest that the benefit of amplification for speech understanding increases over the first few weeks or months of hearing aid use for some listeners. The purpose of this project is to determine the effects of daily hearing aid use on speech recognition abilities and to test one hypothesis regarding an explanation for any changes in these abilities. Specifically, we are exploring whether increases in hearing aid benefit occur over a 6-mo period in novice hearing aid users, and, if so, whether these increases in benefit are accompanied by an increased reliance on high-frequency information in speech. We are also investigating changes in preference for various frequency responses over time.

METHODOLOGY—Three groups of hearing-impaired subjects are being evaluated using the Nonsense Syllable Test (NST) at a signal-to-noise ratio of +20 dB. One control group is composed of experienced hearing aid users who wear their hearing aids daily. Another control group is made up of novice hearing aid users who do not wear their hearing aids outside the laboratory during the study and only wear them during their monthly study visits. The experimental group participants are novice users who wear their hearing aids daily. All hearing aids have been fit binaurally according to the NAL-R prescriptive formula for a moderate-level input with output limiting set to avoid exceeding loudness discomfort. These groups are followed over a period of 6 mo and tested at monthly intervals. At each visit the following measures are performed: 1) the NST in the unaided condition, in an aided condition with the NAL-R frequency response, and in an aided condition with a flatter frequency response (hearing aid benefit is defined as aided minus unaided performance); 2) crossover frequency for NST syllables (this is a measure of the contributions of various frequency regions of speech to speech intelligibility and is the frequency that divides the speech spectrum in half with regard to information used by the listener); 3) subjectively preferred frequency response (NAL-R vs. a flatter response) while listening to a sample of running speech and a sample of music.

Changes in benefit of amplification to nonsense syllable recognition is compared for the three subject groups. If daily use of binaural amplification results in an increase in hearing aid benefit, it is expected that an increase in benefit will be demonstrated only for the experimental group using their prescribed frequency response. If increased reliance on high frequency speech cues is responsible for this change in benefit, it is anticipated that crossover frequency will increase for the experimental group over the study period, but not for the two control groups.

PROGRESS—To date, 14 subjects have been recruited into the control group of experienced users (5 have completed the study), 8 have been recruited into the control group of novice users (3 have completed the study), and 15 have been recruited into the experimental group (4 have completed the study). Software has been developed to play NST stimuli, record responses from a touch screen, and score responses.

RESULTS—Results to date from subjects who have completed at least 3 monthly follow-up visits (11 experienced controls, 4 novice controls, and 8 novice experimental) indicate no consistent group acclimatization effect on speech recognition in any of these groups. This has also been recently reported in other studies of acclimatization with binaural amplification. Interestingly, both groups of novice users are experiencing an increasing preference over time for the high-frequency emphasis response for both speech and music. This occurs whether they wear this response on a daily basis or only once per month in the laboratory. There is also a small trend toward increasing reliance on high frequency cues in speech in both novice groups, although this is not reflected in increased aided speech recognition scores. It remains to be seen whether this will be significant.

FUTURE PLANS—Subject recruitment will continue and data collection completed on 20 subjects in each group for 6 mo following hearing aid fitting. We will also begin to explore the notion of listeners' changing preferences for amplification parameters and try to determine whether they can be influenced, by experience, to prefer those amplification characteristics that optimize speech intelligibility.

[229] IS THERE AN "ACCLIMATIZATION EFFECT" WITH HEARING AIDS?

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C840-RA)*

PURPOSE—In 1992, Gatehouse coined the term "acclimatization effect" to refer to improvement in speech recognition scores seen over time in a small sample of users following the fitting of hearing aids. He believed that the improvements were due to their learning to use the amplified speech cues now available to them, rather than simply to stimulation of auditorily deprived ears. Since that time, however, conflicting data have been reported as to whether or not such a phenomenon exists. The present study will examine this effect with a carefully designed study that attempts to control for test-retest variability of the speech recognition tasks, evaluates the effects of changes in preferred volume wheel setting over time, and uses both linear and nonlinear amplifiers.

METHODOLOGY—Data will be obtained on adults with bilaterally symmetrical sensorineural hearing loss who have and have not previously used amplification. New users will be fitted with binaural sets of both linear and nonlinear hearing aids using probe microphone measurements. Aided speech recognition will be evaluated using the adaptive Hearing-In-Noise-Test (HINT) to determine signal-to-noise ratio (SNR) for 50 percent correct sentence intelligibility and with the Speech-Perception-In-Noise (SPIN) test at a fixed, individually determined SNR. One-half of the subjects will wear the linear hearing aid set home and one-half will wear the nonlinear set home. A unique aspect of this study is that each subject will serve as his/her own control. There will be several repeat sessions measuring binaurally aided speech recognition during a 2-week period prior to the subjects taking the hearing aids home, in order to assess across-session test/retest reliability. Subsequently, repeat measurements will be made at intervals over a 4-mo period, during which subjects will wear the aids on a daily basis. At each of these sessions, testing will be accomplished both with the volume wheel at user-preferred setting and at the original prescribed gain setting. APHAB questionnaire data also will be collected repeatedly to examine any change in subjective impressions of hearing aid satisfaction. Experienced users will be evaluated on the speech recognition tasks with their own hearing aids at a user-selected volume wheel setting fixed across sessions, and also will complete repeat APHABs in order to explore variability.

PROGRESS—To date, data collection has been completed or is underway on 26 subjects (19 new users and 7 experienced users). The early data do not appear to show an acclimatization effect for most of the subjects on the speech recognition tasks; notably, however, the new users have shown relatively high test-retest variability during pre-wearing time and fairly high variability has also been seen for experienced users. Because acclimatization may be greatest for subjects with more severe losses, in whom audibility of speech energy is insufficient without amplification, we are attempting to enroll some subjects in the study who have more severe hearing losses. The questionnaire data are now being analyzed.

IMPLICATIONS—Determination of the existance of an acclimatization effect with hearing aids is crucial because such an effect has significant implications for both clinical practice and research protocols. If there is a period of acclimatization to new amplification, longer trial periods may be necessary prior to measurement of user benefit and decision making regarding changes in electroacoustic parameters.

[230] ACCLIMATIZATION IN MONAURALLY FITTED ADULTS

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PURPOSE—The purpose of this study is to investigate the aided soundfield performance at each of the four discrete volume control settings on the hearing aid. This will be done periodically over a 2-year period in experienced and inexperienced monaurally-fitted adults on the two behavioral measures: the low-predictability (LP) sentences of the Speech Perception in Noise (SPIN) test and the nonsense syllable test (NST).

METHODOLOGY—The first 3–4 months of the study were devoted to subject recruitment from several VA and Speech and Hearing centers, stimulus recording and calibration, and staff recruitment and training. For the last 9 months, we were able to recruit 59 subjects, 23 of whom were excluded from the study on the basis of attrition, change in hearing, or withdrawal. At this time, we have 36 subjects (so far) who remain in the study, of whom 22 were seen for their 3-mo re-evaluation, and 11 for their 6-mo re-evaluation.

PROGRESS—Because the sample size has not, as yet, met the minimum power of statistics, we have not performed a statistical analysis. We are hoping, for the next report, to have culled enough data to enable us to perform a statistical analysis.

FUTURE PLANS—We shall continue recruiting subjects until we meet the minimum statistical-power requirement in order to perform statistical analysis.

[231] EVALUATION OF NONAUDITORY FACTORS THAT AFFECT HEARING AID USE IN ELDERLY VETERANS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C570-2RA)*

PURPOSE—To date there has been no rigorous investigation of the predictive value of assessing various nonauditory factors when considering amplification for the elderly. Limited study with a small sample size, as well as much anecdotal evidence suggests that a large scale, well-controlled study is warranted.

There are no known estimates of successful hearing aid use in the VA population. Numerous authors have acknowledged the influence of visual acuity, manual dexterity, cognition, motivation, and family support on the hearing aid evaluation, selection, and rehabilitation processes with elderly patients.

The key questions of this study are: how do the nonauditory factors affect the use of hearing aids in an elderly veteran population? and do auditory factors relate to predicting hearing aid success in this sample?

METHODOLOGY—Specific aims of this investigation are to evaluate several auditory and nonauditory factors in a group of elderly veterans who are to receive hearing aids through the VHA. Each veteran will receive an initial evaluation which will include the following:

1. An assessment of auditory function.
2. Assessment of nonauditory factors, including visual acuity, fine motor coordination, motivation for improved hearing through hearing aid use, social support, and mental status.
3. Completion of the Hearing Handicap Inventory for the Elderly by each subject.
4. Completion of the Hearing Disability Inventory.
5. A hearing aid evaluation and selection of appropriate devices.

At 4 mo following fitting and dispensing of the selected hearing aids, subjects will be reevaluated on items 1-4 above as well as a Hearing Aid Satistaction Survey, and a Hearing Aid Benefit Inventory.

PROGRESS—To date, 210 subjects have completed the study. Results are encouraging in that they demonstrate the contribution of nonauditory factors to changes in perceived benefit from hearing aid use and to perceived satisfaction from hearing aid use.

[232] DEVELOPMENT OF AN AUTOMATED TECHNIQUE FOR CLINICAL TINNITUS EVALUATION: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #C1693-PA)*

No report was received for this issue.

[233] EVALUATION OF WORD-RECOGNITION PERFORMANCE WITH SENTENCE MATERIALS

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PURPOSE—Evaluation of speech recognition is a complex problem involving many interacting factors from both acoustic and nonacoustic sources. Our task has been to develop a clinical test for assessing speech understanding that is ecologically valid, statistically reliable, and efficient in terms of ease and time of administration. To accomplish this task, we controlled the acoustical properties as well as the psycho-linguistic properties of the speech itself. Our goal was to develop a word recognition measure that uses sentence materials, and isolates linguistic (lexical) sources of variability, and equates psychometric characteristics for individual sentences, providing homogeneous lists suitable for clinical testing using an adaptive procedure. The work of the past year has focused on speech stimuli in a noise background.

METHODOLOGY—The sentence materials we developed combine aspects from several traditional approaches to speech audiometry. Individual word constituents vary with respect to word frequency of usage and phonetic confusibility. In each sentence, three target words are embedded that vary with respect to word frequency and word confusibility. We have isolated several linguistic sources of variability that have never been considered in routine clinical testing, concepts borrowed from the neighborhood activation model of spoken word recognition. Word usage is undoubtedly the single most significant factor biasing word recognition. After each sentence was scaled to produce a common RMS level across the entire set of sentences, the psychometric function relating the intelligibility of each word of each sentence to presentation level across the full perceptual dynamic range of each sentence in a background of speech-shaped noise was determined.

Forty-two nonimpaired controls were tested at five signal-to-noise ratios to determine the psychometric function. Then the following criteria were employed to select a subset of sentences that were homogeneous with respect to their perceptual characteristics. The sentences had to be monotonic in mid-range of the psychometric function; increasing the audibility should always lead to greater intelligibility. Further, any sentence that exhibited extreme properties, either too easy or too difficult, was removed as well. The remaining sentences were then individually adjusted to equate them in terms of intelligibility. The sentences, initially scaled to equal RMS levels, are scaled to equal intelligibility. This process involved determination of the 50 percent point on the function for each sentence, then computing the adjustment in dB to equate the midpoints. This final manipulation produced a sentence test in which each sentence was equally intelligible in the midrange of the psychometric function. This property makes them ideal for adaptive testing methods, since extraneous variation has been largely removed from the sentences through selection and rescaling.

PROGRESS—Studies in the last year have replicated earlier results obtained in quiet with controls and hearing-impaired listeners. Our studies have shown that the difference in intelligibility between often-used words and rarely-used words is as large as 20 percentage points (in the midrange of the psychometric function) when the RMS levels of the stimuli were equated. It is important to note that usage and familiarity are not the same concept. There are many words that we seldom use, yet we know them very well; for example, the word ''violin'' is understood commonly, but in ordinary conversation, it is not a likely word. Another significant variable that we have included in our speech testing materials is the phonetic confusibility of the individual words. We used a metric based on the number of other words in the language that are phonetically similar to a given target word; that is, the number of words that differ by a single phoneme. Words that are phonetically similar to many other words in the language are said to be in dense lexical neighborhoods, and words that are phonetically unique, that is, sound like very few words in the lexicon, are said to be in sparse neighborhoods. Our research has shown that words in sparse neighborhoods are more intelligible than words in dense neighborhoods when overall RMS levels are equated, especially among low-usage words. Remaining work includes the task of rescaling individual words within each sentence to further reduce variability. The data collected thus far have allowed us to calculate the degree to which individual masking patterns will be modified to reduce word-to-word variability.

These sentences will be distributed as a clinical speech test on standard audio media with statistical norms for interpretation stratified by audiometric characteristics and age. The test will: a) identify individuals who have a specific deficit understanding speech when listening in noise; b) be suitable for evaluation of patients with peripheral or central speech deficits; c) provide a means of monitoring progressive disorders or for evaluating rehabilitative interventions; and d) provide a simple, reliable, and efficient screening procedure that could be used in nonclinical environments. The corpus of sentences have been shown to be valid, reliable, and efficient in preliminary clinical trials.

B. Speech Impairment

[234] FEASIBILITY OF PRIMING TO PREDICT CUING-RESPONSIVENESS IN APHASIA TREATMENT: A PILOT STUDY

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PURPOSE—Aphasia, a language disorder resulting from stroke or head trauma, may prevent communication of even the simplest messages and is devastating to the individual and his/her family. The central language dysfunction is a word-finding deficit. Any scientifically grounded rehabilitation intervention is desperately needed for these individuals. The purpose of the present study is to develop a quick, inexpensive prognostic instrument that would save clinicians' time in identifying which aphasic patients will benefit from a semantic facilitation therapy program designed for word-finding deficits. Presently there is no standard method for identifying who might succeed in such a treatment program.

The prognostic instrument involves the semantic priming procedure, which has been studied extensively in normal adults and is grounded in a model of normal word retrieval. Thus, results from this procedure provide insights into the damaged processes and mechanisms underlying word-finding deficits as defined and measured in the normal model. Utilizing such a theoretically motivated procedure to direct the choice of therapy plan is preferable over the trial-and-error approach clinicians currently use.

METHODOLOGY—The prognostic procedure consists of a computerized task and requires approximately 1 hour for administration and scoring. Patients see related and unrelated pairs of words (e.g., lion-tiger; oven-tiger) in addition to word-nonword pairs; their task is to decide if the second word is a real word or a nonword. Reaction times are measured to the millisecond. The list of word pairs is loaded with related word pairs in a high relatedness proportion (RP) condition, but loaded with unrelated word pairs in a low RP condition. In the normal population, RTs are much faster in the high RP condition than in the low RP condition, due to the usage of an expectancy strategy. This strategy is similar to the mental operations necessary for success in semantic cuing therapy, described next.

Treatment consists of a program developed to reinforce the link between semantic representations and their corresponding phonologic codes. Subjects match a picture of an object (used in daily activities) to its name embedded in an array of words containing several related foils, after which they read aloud the correct picture name. A post-test, identical to the pre-test baseline measure, is given upon completion of therapy to measure the cumulative effects of therapy and generalization to untrained, semantically related words. In several reports, semantic facilitation treatment has been shown to be effective in improving word finding, at time intervals up to 1 year post-therapy. Because of the overlap in underlying cognitive operations involved in the semantic priming procedure and in the semantic facilitation therapy program, performance in the priming procedure was examined to determine whether it predicted success in treatment.

PROGRESS—Six fluent persons with aphasia were tested in the pilot study. Positive semantic priming effects were obtained using a procedure that motivated participants to engage in expectancy-based semantic processing. These subjects also showed benefit from semantic facilitation techniques in therapy. In sum, results from the semantic priming procedure predicted that these suubjects would benefit from treatment utilizing semantic cues. Thus, these preliminary results suggest that semantic priming procedure is a useful prognostic instrument to aid clinicians in choosing appropriate therapy for aphasic individuals.

FUTURE PLANS—Based on the promising pilot data, additional subjects with a variety of aphasia types will be tested to determine which individuals will benefit from treatment interventions involving semantic facilitation and cuing techniques.

[235] PROBLEM-SOLVING STRATEGIES OF BRAIN-INJURED AND NORMAL SUBJECTS

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PURPOSE—The objectives of this study are to examine and compare the problem-solving strategies of brain-injured (TBI) subjects and nonimpaired controls and to determine the effects of Strategy Modeling Training (SMT) on the problem-solving efforts of the TBI subjects.

METHODOLOGY—The experimental task in this study is a modification of Mosher and Hornsby's Twenty Questions Task (20Q). In this task the subject sees an array of pictures representing items in common categories (e.g., animals). He is asked to identify the item in the array that the examiner is thinking of by asking "yes" and "no" questions: the object of the game is to identify the item asking as few questions as possible. Subjects meeting selection criteria are administered a battery of cognitive and language tests. Following introduction to the 20Q task, each subject plays three 20Q games to establish a pre-training performance level. Subjects then receive a period of SMT using stimuli that are similar to (e.g., words), but different from those used in the 20Q task (e.g., pictures). SMT teaches the subject to use efficient strategies in solving 200 problems in role-playing situations with the examiner. Following a 1-wk period of no training, three more 20Q games are played by the subject (post-training); a month later, three final games are played (Maintenance).

PROGRESS—So far, our research team has concentrated on the 20Q task performance of two groups, TBI subjects and age-matched controls. Twelve TBI subjects have completed the pre-training, post-training, and maintenance phases of the study. We have developed a means of quantifying the efficiency of subjects' performance on the 20Q task. This uses a 100 mm visual analog scale with anchor points, "not at all efficient" and "highly efficient." Parameters considered include: 1) the use of constraint-seeking (e.g., Is it a form of transportation?) rather than hypothesis-scanning questions (e.g., Is it the airplane?); 2) demonstration of an obvious strategy by the subject in playing 20Q (e.g., Is it in the top two rows?); 3) use of "narrowing" questions after identifying the category containing the target item; and 4) clarity and absence of ambiguity in questions asked. Recently, 20Q performances of 12 TBI and 12 controls were rated for efficiency. The data have not been analyzed.

FUTURE PLANS—We will complete analysis on the data we have as we continue to put more subjects into the project. Initial analyses will assess inter- and intra-judge reliability on the rating procedure. Using a series of Analysis of Variance (ANOVA), we plan to compare the pre-training performances of the TBI and normal subjects. Our expectation is that there will be marked differences among the groups. Next we will attempt to identify those specific aspects of 20Q problem-solving that distinguish TBI and control performance. Next, we will compare the post-treatment and maintenance performances of the TBI subjects with the pre-treatment maintenance performance of the normal performance control. Our hope here is than TBI subjects will improve their 20Q performance secondary to SMT and will therefore no longer differ significantly from that of normal subjects. Initial observations lead us to believe that some TBI subjects improve following SMT and some do not. Individual analyses will then be carried to explain performances of TBI subjects. We plan to analyze individual performances in relation to performance on cognitive and language tests administered to each subject.

[236] QUANTIFYING SPOKEN LANGUAGE HANDICAP IN APHASIA

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No report was received for this issue.

[237] ANALYSIS AND TREATMENT OF APRAXIC SOUND ERRORS

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PURPOSE—Treatment for apraxia of speech frequently focuses on training correct production of incorrectly produced sounds. At the current time, little is known about the generalization effects of such training. That is, it is not clear whether training of specific sounds will result in increases in correct productions of untrained sounds or whether trained sounds will be used correctly in untrained contexts. Therefore, the primary objectives of this investigation are to: 1) determine the stimulus generalization effects of a minimal contrast treatment for apraxia of speech; 2) evaluate the effects of sequential modification of treatment in terms of promoting additional stimulus generalization; 3) study the effects of treatment on general measures of verbal production; and 4) perform acoustic comparisons of correctly and incorrectly articulated sounds, as produced by apraxic patients pre- and post-treatment, in order to examine the relation among such sounds.

METHODOLOGY—Combined single subject and group experimental designs are being used to examine the effects of treatment. Multiple baseline designs across subjects, behaviors, and conditions are being used to evaluate the effects of treatment on production of specific sounds in treated and untreated words across several stimulus conditions within individual subjects. Concurrently, a repeated measures group design is being employed to evaluate the effects of treatment on additional aspects of speech production.

Sixteen apraxic/aphasic subjects will receive treatment, applied individually in a manner consistent with a multiple baseline design. Continuous baseline, treatment, and maintenance probes will be conducted for each individual subject to evaluate production of specific sounds. Additional measures of speech production (e.g., percent consonants correct on consonant inventory, PICA verbal score) will be obtained from each subject prior to and following treatment in order to determine group effects of treatment.

In addition to the preceding pre- and post-treatment measures, samples of incorrectly and correctly produced sounds will be collected and analyzed acoustically. Pre-treatment word lists are prepared for each subject on the basis of performance on a consonant inventory probe. These lists are designed to elicit incorrect productions of sounds that individual subjects misarticulate. Following acquisition of incorrectly produced sounds, word lists are prepared to elicit correct productions of homonymous words. Non-brain-damaged speakers are being matched for age, sex, and regional dialect to each apraxic subject. Correct productions of each of the words utilized in the apraxic speaker's sample are being elicited from the normal speakers for purposes of comparison. Acoustic analyses will be specific to selected sounds and the Computerized Speech Lab is being utilized for the measurements.

PROGRESS—Ten apraxic/aphasic subjects have been entered into treatment to date. An additional two subjects are currently in the baseline phase of the investigation.

PRELIMINARY RESULTS—Acquisition effects of treatment have been positive for all subjects, with the exception of one subject who presented with a combination of apraxia of speech and severe phonemic paraphasia. Generalization to nontraining stimulus conditions has been limited for the majority of subjects, however, treatment instituted in those conditions has resulted in increased correct sound productions.

Acoustic analyses of incorrect and correct sound productions have been completed for five subjects. Results indicate that sound errors produced by these subjects appear to be more like distortions than sound substitutions. Analyses comparing pre- and post-treatment speech samples have revealed positive spectral and temporal changes in sound productions.

RECENT PUBLICATIONS FROM THIS RESEARCH

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A VOT analysis of apraxic/aphasic voicing errors. Wambaugh JL, West JE, Doyle PJ. Aphasiology 1997;11(4/5)521–32.

A critical review of acoustic analyses of aphasic and/or apraxia of speech. Wambaugh JL, Doyle PJ, Kalinyak MM, West JE. In: Lemme ML, Robin DA. editors. Clinical Aphasiology. Austin, TX: Pro-ed; 1996. p. 35–63.

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[238] IMPROVING RESONANCE AND ARTICULATION THROUGH VIDEONASOPHARYNGOSCOPIC FEEDBACK

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PURPOSE—The purpose of this study is to examine the amount of change in speech that results from the use biofeedback therapy using nasendoscopy. Reevaluation after several months will occur to see if changes in speech remain.

METHODOLOGY—Participants were outpatients registered with the Cleft Lip and Palate Facial Program at Bloorview MacMillan Centre. Up to six adolescents and adults scheduled to undergo biofeedback therapy using nasopharyngoscopy were asked to participate. Each participant was seen for six sessions. The first and last session were approximately 2 hrs in length. At the start of the first session each subject underwent the following protocol: hearing screening, completion of a questionnaire to rate his/her speech and understanding of the speech problem, resonance, articulation, and nasometry (i.e., nasalance) assessments, and orientation to the use of nasopharyngoscopic biofeedback. Immediately following insertion of the nasendoscope and just prior to its removal in all sessions, participants were asked to repeat sounds, words and sentences (i.e., probes) without viewing the monitor. These speech samples constituted the baseline, training probe, and post-treatment probes. During the biofeedback portion of the session, the participants viewed the monitor and attempted to respond to the examiner's directions to change the movement of the velopharynx. Biofeedback sessions focused on specific goals based on each person's speech pattern and potential for change. The biofeedback portion of the session lasted up to 30 min. If the subject demonstrated sufficient improvement toward a goal, as determined by clinical judgment, he or she was provided with a home program to complete on a daily basis before the next session. At the end of the last session, each participant provided feedback regarding the biofeedback sessions and received recommendations for future treatment. Each is seen for a follow-up session within 6 mo of the last session. During the follow-up, the protocol completed in the sixth session will be repeated.

PROGRESS—Four participants between the ages of 16 and 55, with diagnoses of cleft lip and palate, took part in the study; three completed it and the fourth decided not to continue after the second session. Data collection has been completed recently; analysis is in progress.

C. Vision Impairment

[239] DEVELOPMENT OF A DATABASE OF CANE TECHNIQUES

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PURPOSE—The goal of the 3-yr study is to construct a database of cane techniques used by blind individuals to establish norms and to evaluate cane techniques over time. This information will be applied to problems of evaluation, development, and design of mobility techniques, accessibility standards, and Electronic Travel Aids (ETAs).

METHODOLOGY—A mobility client profile has been developed in conjunction with the orientation and mobility staffs of five of the VA Blind Rehabilitation Centers (BRCs). Data in the profile is obtained from the mobility instructor, the client, and from visits to the home of the client. Information about travel patterns and use or disuse of cane techniques is recorded before, during, and after training at the BRCs and through follow-up with the client after discharge. Included in this profile is information contained in the RoboCane software package.

RESULTS—The profile was successfully developed in the first year of the project. However, due to clinical staff cutbacks at the BRCs, gathering of information on the full mobility profile has proved to be very problematic. In order to facilitate data gathering, the investigators have expanded the scope of the project to include data gathering and analysis of national Blind Rehabilitation Service information on all rehabilitation programs, not simply mobility. By doing this, we have broadened our scope to include mobility information in the context of the full rehabilitation experience. We have also expanded our sample size to include data from clients seen at all of the 10 BRCs. Data is being gathered on the client's physical status, travel environment, and history of vision rehabilitation services in the Blind Rehabilitation Service Data Base. Information on functional performance of common tasks is being recorded in terms of frequency, need, interest, independence, and satisfaction through the use of the Blind Rehabilitation Service Functional Outcome Survey (on a pre-rehabilitation, post-rehabilitation, and 6-month follow-up basis). Information on satisfaction with programmatic aspects of Blind Rehabilitation is also being gathered. Data on over 700 blinded veterans has been gathered.

FUTURE PLANS/IMPLICATIONS—The data gathered in this study can be used to generate demographic norms for visually impaired individuals in different environments. This data set will be invaluable as a university learning tool for mobility students, practicing mobility specialists, clients, and their families. Perhaps most importantly, these objective measures provide documentation for increased accountability, which results in improved quality assurance, increased capacity for training and monitoring of professional staff, and diminished threat of liability.

RECENT PUBLICATIONS FROM THIS RESEARCH

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New concepts and cane techniques based on research from RoboCane. Blasch B, De l'Aune W, Blasch E. Proceedings of the International Mobility Conference VII; Trondheim, Norway. In press.

The effect of hand position on detection distance for object and surface preview when using the long cane for nonvisual travel. Lagrow S, Blasch B, De l'Aune W. Re:View 1996;28(4):169–75.

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[240] A STUDY OF ILLUMINATION SOURCES FOR LOW VISION INDIVIDUALS

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PURPOSE—The objectives of this 2-yr project were to determine whether specific recommendations for appropriate illumination sources and levels of illumination could be derived for individuals with low vision who read. We studied illumination sources in order to provide professionals with an objective decision-making rationale for lighting recommendations, based on type of visual impairment, type of lighting, and amount of light. We sought to answer four questions: 1) Is there a difference in performance associated with different illumination sources? 2) Are differences in performance associated with different illumination sources also associated with specific visual pathologies? 3) Is there a difference in optimum and preferred illumination? 4) Are differences in optimum and preferred illumination associated with specific visual pathologies?

METHODOLOGY—Seventy-eight subjects with low vision were recruited from in the following categories: 19 with macular loss, 23 with restricted fields, 15 with cataract or other media opacity, and 21 with general amblyopia with no field loss. Each subject who agreed to participate was tested without low vision devices for acuities, field of view, and contrast sensitivity.

The participants were then evaluated by reading a shortened version of the Pepper Visual Skills for Reading Test with a 5× spectacle magnifier under each of the following lighting sources:

- incandescent lighting in a flex arm lamp
- fluorescent lighting in a flex arm lamp
- halogen lighting in a flex arm lamp
- sodium vapor lighting in a flex arm lamp
- full spectrum lighting in a flex arm lamp
- a krypton spectacle mounted lighting device
- an electroluminescent lighting device (developed by researchers at this Center)
- a 5× halogen illuminated hand-held magnifier

After reading the Pepper Test under each lighting condition, participants completed a visual fatigue dairy to indicate a variety of physiological reactions to the type of lighting, and to indicate their subjective preference for each lighting device.

FINAL RESULTS—The data were analyzed to ascertain whether individuals with some pathologies require certain types of lighting for best performance, and to determine whether any relationship exists between specific pathologies and illumination preference. A traditional repeated measures design using various types of illumination was used. There was no relationship between accuracy or rate of reading and the type of illumination used for these subjects. There was no relationship between performance under different illumination conditions and pathology groupings. Variables of age, acuity, field, and contrast sensitivity function had no relationship with pathology group, reading scores, or type of illumination. While there were differences between the illumination type preferred by individual subjects, there was no link between pathology or clinical data.

IMPLICATIONS—We conclude from these results that for a short-term reading task, such as reading bills or mail, readers with low vision must have access to a wide variety of lighting devices in order to find a device that gives best performance, but that no rule base can be ascertained to help professionals to make specific recommendations. Further research is required to discover whether this is true for reading tasks of long duration, such as reading the newspaper.

[241] MEASURING LOW VISION READING ASSESSMENTS USING A SCANNING LASER OPHTHALMOSCOPE

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PURPOSE—We seek to evaluate the efficiency and efficacy of available low vision reading rehabilitation assessment tools using the scanning laser ophthalmoscope (SLO) with the following questions: 1) Do rate, accuracy and error scores on a visual skills for reading test relate to preferred retinal locus (PRL) ability and characteristics as measured by the SLO? 2) Do reading training techniques efficiently and effectively assist readers with macular loss in improving their visual skills for reading? 3) Can the effectiveness of reading training be measured by the improvement in visual skills such as PRL ability/characteristics and/or improvements in reading assessment scores? 4) Are improvements in reading performance related to improvements in different PRL abilities/characteristics or improvements in reading assessment scores which might allow the prediction of the type of reading training that is most appropriate for individuals with low vision?

METHODOLOGY—Software for the SLO has been developed for low vision reading rehabilitation and assessment, so that the Pepper VSRT, the Morgan LVRCA, and the MNRead acuity charts can be presented. This capability allows the investigators to see the visual stimuli (letters and words) on the retina that the patients see when viewing into the instrument and thus determine the interaction between the macular scotoma and PRL. Eighty subjects who have macular degeneration and are interested in reading with low vision devices are being recruited from the Eye Clinic of the Atlanta VA Medical Center. Before rehabilitation intervention, subjects are being assessed with standard clinical testing instruments (e.g., acuity, contrast sensitivity, glare, etc.) and specialized clinical testing, (e.g., SLO macular perimetry, binocular retinal correspondence, and preferred retinal locus testing, including fixation stability, pursuit ability, saccade ability, and word retinal location). Reading performance will be assessed by the Pepper VSRT, the Morgan LVRCA, and the MNRead Acuity charts. These three reading tests will be performed both in their standard method of presentation and in the SLO. Reading rehabilitation is being provided at the Atlanta VA Medical Center using normal accepted training strategies that assist the subjects in maximizing their visual skills for reading.

After the reading rehabilitation is complete, the standard clinical testing, specialized clinical testing, and reading performance assessment is being repeated.

PROGRESS—Programming for the input of the reading tests on the SLO has been completed. The MNRead test, the Morgan Low Vision Reading Comprehension Test, and the Pepper Visual Skills for Reading Tests are being administered via SLO. Subject testing has begun, and 15 subjects have completed the sequence.

FUTURE PLANS/IMPLICATIONS—Following the methods described above will provide this research project with a database of reading performance information as it relates to visual function characteristics of patients. We will be able to determine whether any of the visual function characteristics have an influence on reading performance, training strategies, or outcomes. For example, the error patterns within the Pepper test can be related to macular scotoma and PRL characteristics. This database of reading performance information will also allow the investigators to propose detailed clinical procedures for the optimal training strategies and outcome assessment tools for each individual low vision patient's reading capabilities. The final results of this project will lead to a better understanding of the reading skills and abilities of individuals with macular loss.

[242] DESIGN AND EVALUATION OF LIQUID CRYSTAL (LC) DARK-ADAPTING EYEGLASSES FOR PERSONS WITH LOW VISION

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PURPOSE—The purpose of this three-year project was to develop and evaluate liquid crystal (LC) light/dark-adapting eyewear for individuals with low vision. Many such persons function best under restricted lighting conditions. The purpose of this project was to develop LC sunglasses that very quickly and precisely control the amount of illumination reaching the users eyes and to test the usefulness and practicality of LC sunglasses in actual use by people with low vision.

METHODOLOGY—Initial prototypes were constructed based on an evaluation of LC materials for optical clarity and dynamic light/dark range. Initial prototypes were then tested by a small, diverse, population of 22 people with low vision. Results of these initial tests were employed to re-design the LC sunglasses to make them better match the needs of that population. New prototypes were then constructed for subject testing.

More rigorous testing began in September 1996 of 107 subjects: 23 with central vision loss from ARMD, 32 with cloudy ocular media, 14 with pseudoaphakia, 8 with retinitis pigmentosa, and 30 controls with nonimpaired vision. Measures of acuity, contrast sensitivity, and mobility performance were recorded under varied lighting and glare conditions for all subjects while wearing either no sunwear, their personal choice of the best available sunwear, or the LC prototype. Data included quantified measures of performance, Likert scale subject ratings, and freeform subject comments. All quantitative results (including Likert scale subject responses) were referenced to a "no sunwear" baseline of performance (or response). Verbal comments were grouped by category and counted. Paired t-tests at the 95 percent confidence level were employed to reveal significant performance differences between the prototype and the "best" alternative. Multivariate analyses and least squares means graphs were used to indicate significant differences among the subpopulations. Finally, regression analyses were performed for mobility as a function of acuity and contrast sensitivity. Subject comments formed the basis for specific case studies which complemented the objective findings.

PROGRESS—This project was successfully completed March 1997.

RESULTS—The final prototype employed a flip-up polarizer which provided the LC sunglasses with two light-dark ranges: one range for indoors (68 to 35 percent), and one for outdoors (23 to 2 percent). In general, when subjects wore the LC prototype, their performance on acuity tests, contrast sensitivity tests, and in mobility tests was significantly better than when they wore their choice of the best of alternate sunwear. Of the four population groups with visual disabilities, people with ARMD showed the most improvement in acuity and contrast sensitivity. People with pseudoaphakia showed the most improvement (54 percent) in mobility task performance, while people with ARMD were second with 34 percent improvement. Results also indicated that further improvement could be achieved in all populations by making the glasses become completely clear in darker environments, and by customizing the darkening response to meet the particular needs of the individual.

FUTURE PLANS—Based on the above results, a Small Business Innovative Research grant has been submitted by a company wishing to further develop fast-darkening sunglasses for people with ARMD.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Liquid crystal dark-adapting glasses for persons with low vision. Mancil GL, Ross DA. Optom Vis Sci 1996;73(12s):23.

[243] EVALUATION OF CENTRAL AND PERIPHERAL VISION ENHANCEMENT DEVICES FOR DRIVING

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PURPOSE—In the current phase of the project, we tested the hypothesis that an amorphic lens system could be used effectively by persons with peripheral visual field loss. They would spend the majority of time viewing through a carrier lens, and the amorphic lens would be used for transiently spotting and localizing peripheral visual field information. We also tested whether the clients would benefit from a 12-week training curriculum in the use of the amorphic system for navigation, mobility, and automobile driving.

METHODOLOGY—We recruited 15 persons with peripheral visual field loss due to RP (14), choroideremia (1), or Usher's Syndrome Type II (1), ranging in age from 27 to 67 yrs (mean 45.2 yrs ±13.4). The median visual acuity for this group was 0.12 LogMar (Snellen equivalent approximately 20/25) as measured with the ETDRS charts and protocol. Amorphic lenses are available in minifying powers ranging from 1.2 to 2.0 in increments of 0.2. Lenses were prescribed based on the highest power that could be worn in a walking task without unreasonable side effects. The amorphic lenses were mounted inferiorly on both the left and right carrier lenses.

The Orientation and Mobility (O&M) training was accomplished in 4 weekly sessions, with each week focusing on specific areas of visual function. These areas included locating objects, tracking stimuli, scanning skills, and enhancing visual memory. Following the O&M training, clients began a driving training curriculum consisting of 8 weekly sessions within the grounds of the Hines VA Medical Center. Once again training focused on specific skills related to the use of the amorphic lens system for driving.

PROGRESS—Subjects were divided into two groups equivalent in age, visual acuity, mean horizontal field extent, and mean contrast sensitivity. The study utilized a cross-over design in which Group A received the training during the first 3 mo of the 6-mo study, and Group B received the training during the second 3 mo. All were administered clinical vision, psychophysical and laboratory, O&M, and driving assessment tests without the amorphic lenses on the first assessment day as a baseline measure (Test Day 1). Group A was then given their lenses and trained on the laboratory and driving curriculum. Group B did not receive the lenses nor the training during this period. At 3 mo, all subjects were again tested with the assessment battery (Test Day 2): Group A with the amorphic lenses, Group B without. During the next 3-mo, Group A kept the lenses, but received no further training; Group B received the lenses and were trained on the laboratory and driving curriculum. At 6 mo, all were tested with the assessment battery with the amorphic lenses (Test Day 3).

For the purpose of subsequent analyses, the 203 individual tasks within the assessment tests were coded according to the primary visual skill involved in the task. These visual skills included: recognition (43), peripheral detection (46), scanning (61), tracking (19), visual memory (19), and mobility (21).

RESULTS—Overall for both groups combined, the percentage of tests improved ranged from 46.4 percent in the mobility category to 27.0 percent in the scanning category, with an overall improvement of 37.3 percent. Those subjects with initially smaller visual field extents showed a greater percentage of peripheral detection tests showing improvement following training with the lenses ($r(14)=-0.54$, $p<0.05$). In addition, those with initially smaller visual field extent showed a greater percentage of scanning tests showing improvement following training with the lenses ($r(14)=-0.62$, $p<0.02$).

We found improvement in visual functioning within all the broad skills categories with training in the use of a bioptic amorphic lens system. There was greater improvement for those with smaller visual field extents in peripheral field-related tasks.

FUTURE PLANS—We are presently conducting Phase 2 of this project, in which we are investigating the effectiveness of bioptic telescopic lenses for driving and other functional tasks in persons with central vision loss.

RECENT PUBLICATIONS FROM THIS RESEARCH

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The effects of random element loss on letter identification: Implications for vis loss in patients with retinitis pigmentosa. Seiple W, Holopigian K, Szlyk JP, Greenstein VC. Vis Res 1995;35:2057–66.

[244] MICROPHOTODIODE TILES AS PROSTHESES FOR THE RESTORATION OF VISUAL FUNCTION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C1569-RA)*

PURPOSE—In many blinding conditions, the photoreceptor cells are primarily affected while other layers of the neural retina are spared. In these cases, restoration of photoreceptor function could lead to recovery of lost vision. The overall purpose of this project is to determine whether this can be accomplished using semiconductor-based photodiodes placed in the subretinal space. In the report period, we have evaluated whether tunicamycin treatment of the cat eye provides a suitable model of photoreceptor degeneration and placed implants into the subretinal space of normal untreated cats.

METHODOLOGY—To evaluate its effectiveness, 1 mg of tunicamycin was dissolved in 10 ml DMSO and injected into the vitreous chamber of one eye of three adult cats; the fellow eye received vehicle alone. Retinal function was evaluated by electroretinography in sedated cats (11 mg/kg ketamine; 2 mg/kg xylazine). Retinal architecture was evaluated by light microscopy and immunocytochemistry using a polyclonal antibody against the Na,K-ATPase catalytic subunit.

Photodiodes ~1.5 mm in diameter and 50 μm thick, that respond electrically to light from 500 to 1100 nm were implanted in adult cat eyes using sterile surgical techniques under halothane (0.8 percent) anesthesia. An incision made in the temporal sclera provided access to the vitreous chamber and retina. A retinotomy was made and a small amount of saline was injected to create a retinal bleb. A partial vitrectomy created a channel from the scleral incision to the retinotomy site that was filled with Healon. The implant was positioned near the retinotomy opening with a plastic carrier and then moved into the subretinal space. After the scleral incision was closed the cat was awakened and received postoperative antibiotic treatment. The appearance of the retina was evaluated by indirect ophthalmoscopy. In addition, electrical responses were recorded from sedated cats to infrared (IR) stimuli, which isolate implant-mediated responses from those of the native visual system.

PROGRESS—Tunicamycin induced a panretinal degeneration that affected all cellular layers. Successful implantations, defined by the maintenance of a stable subretinal implant position and the retina remaining attached over the implant site, have been made in four cats. Electrophysiological recordings have been made using IR stimuli to isolate implant-mediated activity. These indicate that the implant functions in the subretinal space.

RESULTS—The electroretinogram of tunicamycin-treated eyes was reduced to ~15 percent of that of the normal eye. Histological analysis indicated that all retinal layers were affected. Tunicamycin treatment induced marked alterations in the differential distribution of the Na,K-ATPase within the retina. The location of the implant has remained stable in all four animals. Animals have been evaluated electrophysiologically at monthly intervals using IR stimulation. These recordings establish that the implant functions electrically within the subretinal space. Over time, the implant response increases in amplitude.

FUTURE PLANS—We plan to follow these, and additional cats with subretinal implants, for extended periods of time. This will allow us to examine the long-term functionality of the implant and the stability of the electrical responses that have been seen. In addition, cortical recordings are being made to determine whether implant activity is sufficient to stimulate the visual pathway. Biocompatibility will be assessed histologically at designated time points. In addition, smaller scale implants are being fabricated that can be more easily introduced into the subretinal space. Finally, we are working to develop an animal model of photoreceptor degeneration that can be used to evaluate the possibility that the implant will restore visual function to a retina that suffers from a retinitis pigmentosa-like disorder.

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The effect of increased intraocular pressure on retinal potentials induced by subretinal microphotodiode array electrical stimulation. Peyman GA, Chow AY, Liang C. Peachey NS. Invest Ophthalmol Vis Sci 1996;37:S349.

Subretinal implantation of a high density microphotodiode array in the cat retina. Perlman JI, Chow AY, Peachey NS. Invest Ophthalmol Vis Sci 1996;37:S96.

[245] LOW VISION ENHANCEMENT SYSTEM (LVES)

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(Project #C638-2DA)

No report was received for this issue.

[246] DEVELOPMENT OF THE SCANNING LASER OPTHALMOSCOPE FOR LOW VISION REHABILITATION: PHASE 2

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420*
(Project #C838-2RA)

PURPOSE—The vast majority of people with impaired vision retain some functional vision with which to perform everyday tasks and are characterized as persons with low vision. Currently there are no clinically practical means for accurately and precisely measuring their scotomas and preferred retinal loci for visual tasks. In addition, there is neither a reliable or efficient method for training eccentric viewing at optimal retinal areas nor for evaluating the effectiveness of the current training which require many man-hours to accomplish. Therefore, although low vision rehabilitation effectively incorporates compensation for impaired acuity (e.g., training and devices like magnifiers, CCTVs, and LVES), low vision rehabilitation specialists have no means for effectively compensating for impaired visual function due to macular scotomas, a condition affecting a significant proportion of the low-vision population. The project objective is to develop the scanning laser ophthalmoscope (SLO) as an effective and efficient low vision rehabilitation system.

METHODOLOGY—To accomplish this objective, evaluation/treatment procedures on the SLO have been developed with a Windows NT computer graphics/imaging system using the Targa 2000 Pro graphics/imaging board (TrueVision Inc), called the Scanning Laser Ophthalmoscope Low Vision Rehabilitation System (SLO LVRS). The specific clinical testing modules developed are: 1) software to measure precisely and accurately scotoma and preferred retinal locus (PRL) locations and PRL abilities, 2) algorithms to perform automated retinal image registration, 3) software for teaching and evaluating eccentric viewing training, and 4) software for low vision patient management. In addition to the software and hardware development, investigation into the intellectual problems has begun. For example, the parameters for computer automated image registration have been explored so that scotoma measurements and PRL abilities can be performed quickly and efficiently.

PRELIMINARY RESULTS—Beta testing of the modules is being done at the VICTORS program at the Kansas City VA Medical Center, the Visual Independence Program of the Eye Foundation of Kansas City, the Low Vision Service of the Retinal Consultants of Southwest Florida, and the Rehabilitation Research and Development Center at the Atlanta VA Medical Center.

Extensive work into the laser power and spatial field characteristics of the SLO has been done both for short-term (daily) and long-term (monthly) reliability. The stability of the laser power as well as the homogeneity of the SLO display field requires monthly calibration protocols to assure the proper quality control in the clinical testing. However, the magnification changes in the SLO image due to emmetropia for most patients does not require special optical correction. Reliability (test-retest and inter-tester) of the methods for macular perimetry and PRL ability testing was evaluated and new methods have been developed and incorporated into SLO LVRS to increase the reliability. The characteristics of the PRL movement during fixation alone and while performing the fixation task during perimetry have been determined to indicate the range of retinal movements (direction and size) that must be monitored by the computer-automated registration. A Hough Transform image registration algorithm is being developed for computer automated registration of SLO images.

FUTURE PLANS—Validity evaluations of the methods for macular perimetry and PRL ability testing will be performed. Reliability and efficacy of eccentric viewing training with SLO LVRS will be evaluated at the beta test sites. The SLO LVRS will be installed at additional VA Medical Centers as funding from these individual centers allows.

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Characteristics of dominant PRLs and implications for low vision rehabilitation. Schuchard RA, Fletcher DC. Optom Vis Sci 1996;S73:133.
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[247] FACTORS LEADING TO DISUSE OF LOW VISION DEVICES BY VISUALLY IMPAIRED ELDERLY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #C814-2RA)*

PURPOSE—In this 3-yr study, the project team is evaluating long-term usage patterns of low vision devices by older veterans to identify causes of disuse of previously successful devices. In the past 2 yrs, we have established a representative sample of older adults who have low vision; provided comprehensive low vision care for each subject in order to prescribe the most appropriate low vision device to address that person's specific goals; collected base-line data on selected ocular, physical, and psycho-social characteristics of each subject (pretest); and implemented a monitoring system to document usage patterns over time. Currently, we are repeating low vision clinical and the base-line data set at any time a device is deemed no longer of use by a subject (post-test); and establishing correlations to identify factors which lead to disuse of the prescribed low vision devices. Late in the project, a panel of experts will be convened to evaluate the research results and make recommendations pertinent to the activities of manufacturers, clinicians, and funding agencies.

METHODOLOGY—Over 125 subjects, aged 65–95, with low vision enrolled in this project. Entry level data (baseline) was collected in four ways: a thorough patient interview, including the Adaptation to Vision Loss Scale, the Mini-Mental State Exam, the Health Status Questionnaire, the Geriatric Depression Scale, and the Functional Assessment Inventory); an eye health evaluation with photodocumentation (to determine the cause of low vision); a standardized low vision device evaluation (to determine personal goals and visual abilities, and evaluate devices to fulfill those goals); and a "criterion referenced" low vision device-training protocol. Subjects were then prescribed the devices found successful for their stated goals. Finally, subjects entered the monitoring portion of the study where they were mailed a large-print post card with a visual analog scale monthly for the duration of the project. Subjects indicated their level of satisfaction for each device. If their level varied from the initial post-training baseline by a significant amount, they were asked to return to the clinic for post-test assessment ("unsuccessful users"). Twenty five successful users were randomly chosen to undergo post-test assessment that would confirm no problems existed. Of those 25, 7 were also randomly selected to undergo a home visit where the low vision training specialist collected clinical data (by repeating many of the clinical tests in the home setting) and functional data (asking the subject to perform the tasks they commonly complete with the devices in their own way). In this way, the accuracy of the monitoring system was evaluated.

PROGRESS—A total of 131 subjects completed the project protocols including the interview, eye health evaluation, low vision device evaluation, extensive low vision device training, and entering the follow-up program. Of these, 13 have discontinued for a variety of reasons: 3 are deceased; 10 are too ill, have moved, or are not willing to continue. One hundred eighteen people are currently receiving monitoring cards, with an average of five devices per subject, (i.e., approximately 600 devices are being followed). Data are currently being input and coded for in-depth analysis.

FUTURE PLANS—Subjects will be monitored at least through 1997 and analysis will be completed thereafter. A panel of experts will then be convened to evaluate project findings and make recommendations regarding device design/modification, implications of service delivery models, and applications in clinical practice. Final data analysis and final reporting will then be completed.

XIV. Spinal Cord Injury and Related Neurological Disorders

A. General

[248] SPINAL CORD INJURY-INDUCED BONE LOSS

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PURPOSE—We hypothesize that changes in neuropeptides and neurotransmitters in nerves supplying bone and/or bone marrow osteoprogenitor stem cells are involved in the osteopenia which develops as a result of spinal cord injury (SCI). It is important to understand how these changes affect bone metabolism after SCI, since a considerable number of veterans are paralyzed from SCI. The significance of the research lies in the potential for discovering the mechanism(s) involved in the osteopenia following SCI. These results could lead to a therapy to prevent the loss of bone in newly injured veterans, or aid in the recovery of bone in chronic SCI veterans.

METHODOLOGY—The studies utilize a rat model in which the bone loss is both dramatic and progressive over time. Histomorphometry, radioimmunoassays, and molecular biology techniques characterize bone loss following SCI, as well as changes in neuropeptide distribution and levels in bone. We have focused on calcitonin gene-related peptide (CGRP) and vasoactive intestinal peptide (VIP), both are in nerves in bone and implicated as modulators of bone metabolism. Immunohistochemistry, receptor binding, and autoradiographic methods are used to evaluate receptor changes in bone and in osteoprogenitor cells obtained from bone marrow.

PROGRESS—We have defined the model and histomorphometrically evaluated the effects of SCI on the bone at various times postlesion. We have developed methods to isolate bone cells and osteoprogenitor stem cells from bone marrow for *in vitro* evaluation from the bones of lesioned animals, as well as to evaluate the neuropeptide content and respective mRNAs. We have established a human bone cell model to evaluate the effect of neuropeptides on proteins involved in cell-cell communication via gap junctions. We have shown gap junctions to be functionally regulated by VIP and CGRP in these cells.

RESULTS—As the animals age with SCI, they lose approximately 60 percent of their trabecular bone (below the lesion) compared to nonlesioned animals. This loss results in loss of femora mechanical strength. Immunohistochemical and retrograde tracing studies showed that sensory nerves containing CGRP and VIP are particularly dense in the periosteum and penetrate the bone. VIP is capable of acutely up-regulating the mRNA for the gap junction protein, connexin 43, in osteoblasts. CGRP is capable of regulating osteoblast function via potassium channels and intracellular calcium, but with moderate increases in cAMP, suggesting other second messengers for CGRP. We have cloned and characterized a human and murine CGRP receptor component protein (RCP) cDNA, developed antibodies to this RCP, and are currently working on the mechanism of how this component of the CGRP receptor functions. We have begun anatomical/developmental studies to evaluate the presence and distribution of CGRP, the CGRP receptor, and the CGRP receptor component protein during development. We have shown that the osteoprogenitor stem cells from bone marrow are affected by CGRP in terms of increasing the number of osteogenic cells obtained from marrow cultures, as well as demonstrating the neuropeptides are capable of increasing the mineralization *in vitro* of the osteogenic cells.

FUTURE PLANS—We will continue our studies with bone and bone marrow osteoprogenitor cells of lesioned and nonlesioned animals for neuropeptide effects on mRNA levels and functional status of cell-cell communication, as well as on mineralization of collagen matrix formed *in vitro*. We are beginning studies to identify post-SCI changes in osteogenic precursor cells from bone marrow for these neuropeptides. We will continue our studies on the mechanism of CGRP and CGRP-RCP modulation of osteoblasts and on bone marrow-derived osteoprogenitor cells in animal and human bone and osteoprogenitor cells.

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[249] EFFECT OF SUPPORTED STANDING AND UPPER BODY EXERCISE ON LOWER EXTREMITY SPASTICITY IN PERSONS WITH SPINAL CORD INJURY

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PURPOSE—The purpose of this research was to demonstrate that supported standing and/or aerobic upper-body exercise significantly alters signs of upper motor neuron syndrome (UMNS), particularly lower limb tone, in persons with spinal cord injury (SCI).

METHODOLOGY—Twenty-nine subjects with SCI (28 males, 1 female, aged 26 to 63 years, mean: 45.4) were recruited for the study. All reported a history of increased tone and/or spasms in the legs. Time since injury: 1–35 years (mean: 9.6). All but three were receiving pharmacologic treatment (Valium, Baclofen, Diazepam) for ''spasticity;'' all were instructed not to discontinue these or any other medications and were asked not to engage in any physical exercise, stretching, or ranging prior to any of the experimental conditions. Thirteen withdrew from the study at various points for personal and/or medical reasons; four failed to demonstrate sufficiently increased tone to qualify for further participation (relaxation index >0.85). The remaining 12 (8 with paraplegia, 4 with quadriplegia) completed all phases of the experimental protocol, completing three procedures. To test the effect of moderate-intensity aerobic upper-body exercise on signs of UMNS, subjects performed 20 min of submaximal wheelchair ergometry exercise. To examine the effect of low-intensity activity, subjects completed 40 min of supported standing in a commercially available standing frame. A timeout (control condition) was included to isolate effects of physical activity from changes occurring during quiet rest and testing procedures alone. Baseline measures of tone were followed immediately by an experimental condition (upper-body exercise, standing, or timeout). To examine the temporal pattern of changes in tone following the experimental condition, measurements were repeated immediately following activity or timeout and at 90-min intervals for 3 hrs.

Tone at the knee was assessed by the pendulum drop test. Electrogoniometers were strapped on the lateral side of each knee, and the subject was placed in as near to supine position as contractures permitted. The subject's legs were alternately lifted to a set position near horizontal then released to swing freely about the knee. Subjects capable of voluntary muscle contraction were instructed to remain relaxed, and rectus femoris activity was visually and aurally monitored. Calibrated electrogoniometer voltages were computer-sampled at 200 Hz. The legs were dropped alternately six to eight times, and the average normalized relaxation index (R2n) for the series was computed with outliers omitted. R2n is a normalized ratio of the angular deflections of the limb in each direction from its final dependent resting position. Values of ~1.0 are obtained for normotonic limbs and <1.0 for hypertonic (spastic) limbs; hence, increased R2n indicates an improvement in hypertonicity.

RESULTS—Average R2n for the group increased more following physical activity than timeout with relatively greater increases occurring later in the measurement period. Specifically, R2n increased 14.3 and 13 percent immediately after exercise and standing, respectively, compared to a 10.1 percent increase immediately following timeout. In contrast, increases in R2n observed 3 hrs after exercise and standing were 20.8 and 23.1 percent, respectively, while the increase in R2n 3 hrs following timeout was 6.6 percent.

IMPLICATIONSIf the signs of upper motor neuron syndrome such as hypertonicity can be moderated with exercise, many benefits accrue, including significantly reduced cost of treatment, absence of side effects, and increased control at the disposal of the individual. In addition, facilitation of a healthier lifestyle should decrease the incidence of medical complications secondary to spinal cord injury, contributing to further reductions in the cost of providing health care for these persons.

[250] TRANSPORT OF NGFS±MIF-1 INTO SPINAL CORD

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PURPOSE—Cytokines like tumor necrosis factor-α (TNF) can exert many effects on the central nervous system (CNS). There is evidence that TNF can affect glial cell proliferation and stimulate the synthesis of nerve growth factor, thereby contributing to spinal cord regeneration. Although both TNF and interferon-γ exert mainly proinflammatory effects, IFN-α exerts mainly immunosuppressive effects. Their entry into the spinal cord was investigated.

METHODOLOGY—Using sensitive techniques, we studied the penetration of TNF from the periphery into the spinal cord in rats with acute spinal cord injury, experimental autoimmune encephalomyelitis (EAE), and in normal mice. Multiple time-regression analysis was used to measure the rate of entry of the cytokines into the CNS. In normal mice, the permeability was compared with that of interferon-α and interferon-γ. Additional techniques that were used included reversed phase high performance liquid chromatography (HPLC) and acid precipitation to verify the intact nature of the recovered cytokine and capillary depletion with perfusion to demonstrate that the material was not bound or adherent to the endothelial cells of the capillaries comprising the blood-spinal cord barrier.

PROGRESS—After complete transection of the lumbar spinal cord of mice, there was increased permeability to TNF in the lumbar region proximal to the lesion; the transport was saturable. This increase was significantly greater than that seen with sucrose, a smaller molecule, or with albumin, a molecule similar in size to TNF. For ebiratide, an MSH/ACTH analog of six amino acids, there was no increase in penetration of the spinal cord after lumbar transection, again emphasizing the selective nature of the increased permeability to TNF that cannot be explained by simple disruption of the blood-spinal cord barrier.

In EAE, saturable transport of TNF into the spinal cord was highest in the lumbar region and was greater than that seen with albumin. In both EAE and the spinal cord transection model, the increased transport of TNF was paradoxically greater than could be explained by the leakiness accompanying these conditions. It appears that the saturable transport of TNF into the spinal cord is activated by EAE and by transection of the lumbar spinal cord.

Although the interferons entered the spinal cord after peripheral administration to a greater extent than into the brain, for the most part the entry was not saturable. Only in the cervical region of the spinal cord and only for interferon-γ was saturation of the radioactively labeled cytokine seen after co-administration of excess unlabeled interferon-γ, but the highest dose used was only 1 μg. For each region, the penetration of interferon-α was greater than that for interferon-γ. TNF was used for comparison, and again its entry was saturable in all three regions of the spinal cord: cervical, thoracic, and lumbar.

In each study in normal animals there was a greater penetration of every substance tested into the cervical and lumbar areas of the spinal cord in comparison with the smaller rate of penetration into the thoracic region of the spinal cord.

FUTURE PLANS—The permeability of the spinal cord to neurotrophins will be studied next.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Differential permeability of the BBB in acute EAE: enhanced transport of TNF-α. Pan W, Banks WA, Kennedy MK, Gutierrez EG, Kastin AJ. Am J Physiol 1996;34:E636–42.

[251] CAUSE OF MALE INFERTILITY AFTER SPINAL CORD INJURY AND ITS PREVENTION

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PURPOSE—The purpose of current experiments was to investigate the efficacy of hormone replacement in the prevention of regression of spermatogenesis after spinal cord injury (SCI) and to determine whether disruption of neural supplies to the testes might contribute to the chronic effects of SCI on spermatogenesis.

METHODOLOGY—SCI was induced in adult Sprague-Dawlay rats by surgical transection of the spinal cord at the level of the 9th thoracic vertebrate. Immediately following the surgery, the rats were given daily injection of FSH, implantation of 2×5 cm testosterone capsules (TC) or combination of both. Animals were hemicastrated 1 mo later. The hemicastration unexpectedly resulted in heavy loss of the SCI animals. This is due to the loss of voiding capability of the animals and rupture of the bladder is the major cause of death in the hemicastrated animals. The surviving animals were killed 2 months later (3 mo after the SCI).

For testicular denervation, the testes of adult rats were exposed through a mid-scrotal incision. The superior nerve (SSN) and inferior spermatic nerves (ISN) were isolated from the surrounding fat tissues and dissected. Testicular tissues were fixed in Bouin's solution and processed for histology or preparation for whole mounts of seminiferous tubules. Quantitative analysis of spermatogonial proliferation was performed on whole mounts of seminiferous tubules. The status of spermatogenesis was evaluated in testicular histology.

RESULTS—Four weeks after SCI, abnormal spermatogenesis was evidenced by the presence of lesions such delayed spermiation, vacuolization of germ cell nuclei, phagocytosis of mature spermatids, and incomplete cellular association. In addition, the numbers of A1 and B spermatogonia and preleptotene spermatocytes were reduced by 20–30 percent. Administration of FSH, testosterone, or a combination of both did not prevent the decrease in spermatogonial proliferation. Testicular histology revealed that spermatogenic lesions in SCI rats receiving FSH were far more extensive than that in the untreated SCI rats. Testosterone alone, however, attenuated the severity of spermatogenic lesions in SCI rats. These results suggest that deprivation of FSH and testosterone during acute phase of SCI is not the sole reason for the decrease in spermatogonial proliferation and spermatogenic lesions in SCI rats.

Three months after the surgery, regression of spermatogenesis in SCI rats without hormone replacement had attained its maximum. In two SCI rats receiving FSH and testosterone, active spermatogenesis was observed in 21 and 100 percent of the seminiferous tubules and qualitatively complete spermatogenesis was observed. These results demonstrated that combination of FSH and testosterone replacement is beneficial for the recovery of spermatogenesis in SCI rats.

Four weeks after denervation of the SSN, alteration of spermatogenesis was evidenced by the presence of lesions including phagocytosis of mature spermatids, incomplete cellular associations and incomplete spermatogenesis. However, delay or failure in spermiation did not occur in the denervated testes. Denervation of the ISN did not affect spermatogenesis. Quantitative analysis of spermatogonial proliferation in whole mounts of the seminiferous tubules revealed that normal numbers of Aal, A1, and B spermatogonia and preleptotene spermatocytes were maintained. These findings indicate that while testicular denervation will result in abnormal spermatogenesis, the mechanisms leading to these changes are different from that occur after SCI. In addition, testicular denervation does not contribute to the decrease in spermatogonia proliferation during acute phase of SCI.

By 3 months, spermatogenesis in SSN denervated testes was totally regressed as that occurs in chronic SCI rats. These results suggest that denervation of SSN as a result of SCI may contribute to the final regression of spermatogenesis in SCI rats.

IMPLICATIONS—Results of these experiments demonstrate that both endocrine deprivation and testicular denervation could contribute to the SCI-induced regression of spermatogenesis, perhaps through different mechanisms. Thus, multiple modalities could be considered to preserve spermatogenic function in SCI men. Enhancement of spermatogenic recovery in SCI rats by combinations of FSH and testosterone replacement indicates that hormone replacement during acute phase of SCI may be effective for the maintenance/recovery of spermatogenesis in SCI men. However, further experiments are required to provide better understanding of cellular or biochemical mechanisms responsible for the SCI-induced spermatogenic lesions. In addition, the effective dose of each hormone and duration of replacement must be optimized in animal model so that such approaches can be applied in SCI men to achieve a maximal recovery of spermatogenesis.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Suppression and recovery of spermatogenesis following spinal cord injury in the rat. Huang HFS, Linsenmeyer TA, Anesetti R, et al. J Androl. In press.

[252] MANUAL WHEELCHAIR USER UPPER EXTREMITY PAIN

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B869-2RA)*

PURPOSE—This project has two primary objectives: 1) to perform a detailed biomechanical analysis of the upper extremity during wheelchair propulsion, and 2) to identify specific biomechanical factors that differentiate manual wheelchair users with and without pathologic findings such as carpal tunnel syndrome and rotator cuff tears.

METHODOLOGY—Before the experimental trials, each subject was familiarized with the testing protocol, then gave informed consent. A bilateral kinematic analysis system, OPTOTRAK (Northern Digital Inc.), was utilized for this study. Two carbon fiber composite rigid bodies, composed of three markers each, were used to identify head and trunk motions. Each rigid body had three LED markers, creating an isosceles triangle. Fourteen additional markers were used to identify anatomical landmarks on the upper extremity. Markers were placed on the subject's right and left: acromion process, lateral epicondyle, olecranon process, ulnar and radial styloid, and second and fifth metacarpophalangeal joint.

The subjects propelled in their personal wheelchair during the entire testing session. Each subject's wheelchair was fitted with a force and torque sensing pushrim, the SMART$^{\text{Wheel}}$ to measure three-dimensional forces (Fx, Fy, Fz) and moments (Mx, My, Mz) applied to the pushrim during wheelchair propulsion. There were no other adjustments made to the wheelchair, and the implementation of the SMART$^{\text{Wheel}}$ did not change the camber or diameter of the normal pushrim or tire size.

The subjects pushed on a wheelchair dynamometer prior to the testing period in order to acclimate themselves to the experimental set-up. Then they were instructed to propel their chairs at a self-selected speed, 0.9 m/s, 1.8 m/s, and for a ramp up to maximum speed. Kinematic and kinetic data were collected for 20 s during each trial. The subjects were allowed to rest approximately 1 min between each condition.

PRELIMINARY RESULTS—To date we have tested over 30 manual wheelchair users. The analysis of the data encompassed the motion, forces, and moments occurring at the shoulder and wrist joint. Shoulder abduction, sagittal extension, sagittal flexion, external rotation, internal rotation, and horizontal flexion angles have been calculated using an anatomically based coordinate system. The associative moments have also been calculated. The glenohumeral joint (GHJ) to acromion, acromion to GHJ, anterior to posterior (AP), PA, compressive, and distractive forces were also calculated.

At the wrist maximal flexion, extension, radial deviation, ulnar deviation, supination, and pronation angles have been described, along with compressive, distractive, radial-ulnar (R-U), U-R, palmar-dorsal (PD), and DP. The maximal moments that tend to flex, extend, radial deviate, ulnar deviate, supinate, and pronate the wrist have also been calculated in an anatomically based system.

FUTURE PLANS—The next stage of our study is to identify the subjects with and without pathological findings, such as carpal tunnel syndrome and rotator cuff tears. Coupled with the biomechanical measures, we are anticipating that we will find biomechanical characteristics that contribute to injury. Future research directed toward prevention of secondary injuries in manual wheelchair users by optimizing wheelchair fit and configuration.

[253] PERFORMANCE CAPACITY AND PHYSICAL STRAIN IN SUBJECTS WITH A SPINAL CORD INJURY

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Sponsor: *Dutch Prevention Fund*

PURPOSE—We study the evolution in physical capacity, physical strain, and risk factors for cardio-vascular and musculo-skeletal disease over time in wheelchair-dependent individuals with spinal cord injury (SCI). Parameters of performance capacity and physical strain in ADL are evaluated with repeated standardized wheelchair exercise tests as well as ADL tests in different groups of subjects with SCI, both subjects with a long-standing SCI—sedentary as well as physically active subjects—and those in the course of rehabilitation. Thus the effects of wheelchair use and a wheelchair-confined lifestyle on performance capacity, wheelchair propulsion technique, and cardio-respiratory (and musculo-skeletal) parameters, as well as the risk factors for cardio-vascular disease are evaluated.

METHODOLOGY—Both cross-sectional and longitudinal study experimental designs are used, involving male as well as female subject groups and sedentary as well as physically active individuals. Different subject groups were studied in both cross-sectional as well as longitudinal research designs in the course of the rehabilitation process. Maximum aerobic capacity, anaerobic wheelchair sprint performance, and isometric strength are individually determined in standardized testing procedures at fixed times during and/or after rehabilitation. The physical strain of daily life, and more specifically the therapy sports activities, are simply evaluated with the Percentage Heart Rate Reserve (%HRR) with a SportTester PE4000. Risk factors for cardio-vascular disease (blood pressure, cholesterol, and so forth) and musculo-skeletal problems are repeatedly determined with questionnaires that are also used to study different physical and personal characteristics.

RESULTS—The results on both recently injured, intramurally treated, persons with SCI and those with long-standing SCI indicate an inverse association between physical strain in standardized ADL wheelchair tasks and indicators of maximum performance capacity. Physical strain during rehabilitation does not meet criteria for training as formulated by the American College of Sports Medicine. Intensity, duration, and frequency of physical activity should be increased and tuned more carefully to the individual. Findings on risk indicators for cardio-vascular disease do not show an increased risk among the subjects with SCI at study. Physical or sports activities have a significant reducing effect on such risk factors among subjects with longstanding SCI and those involved in rehabilitation, both high- and low-level lesions.

FUTURE PLANS—A further analysis of the effects of the physical activity components within the rehabilitation process upon performance capacity in subjects with SCI is planned to be conducted in a randomized clinical trial. Additionally, the evolution of wheelchair propulsion technique will be studied over time as a mediating component of performance capacity. Thus, we hope to grasp the process of learning in this complex motor task.

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[254] A MYOELECTRIC SWITCH FOR COMMUNICATION AND COMPUTER ACCESS

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PURPOSE—The purpose of this project is to develop a wireless myoelectric switch for communication and computer access. The switch allows individuals who are paralyzed to operate these devices with the contraction of any muscle in the body. For those with advanced Amyotrophic Lateral Sclerosis (ALS) the myoswitch allows them to use their facial muscles for control since these are often the last muscles to be spared. A wireless version of this switch improves on the reliability and cosmesis of the myoswitch.

PROGRESS—A circuit board that incorporates a precision instrumentation amplifier and a digital 900 MHZ RF transmitter has been designed. The requirement for a low voltage power supply (3 V lithium battery) and low power, favored radio frequency (RF) as the technology of choice. RF has the further advantage that it can be transmitted through clothing and other material that may intervene between the transmitter and receiver. The circuit measures 3.81 by 1.59 cm and is small enough to tape to a user's face above any contracting muscle. The antenna is contained within the circuit board. The transmission range, limited by the small antenna size, is approximately 3 m, which is adequate for the application. Current consumption during transmission is approximately 20 mA while the quiescent current consumption is less than 1 mA.

FUTURE PLANS—Identification of a power source for the transmitter remains a significant challenge. Although battery technologies that meet the power requirements and the size constraints of this application do exist, the packaging shape and size required for this application is not readily available commercially and no rechargeable batteries that meet these requirements have been found. As battery technologies for consumer applications rapidly evolve, however, we expect to overcome these challenges within the next year.

[255] CAUSES AND COSTS OF UNPLANNED REHOSPITALIZATIONS AMONG PERSONS WITH SPINAL CORD INJURY

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PURPOSE—There have been several published studies of rehospitalization rates, risk factors for rehospitalization, and associated costs among persons with spinal cord injuries (SCI). However, only limited baseline data on the long-term incidence of a few secondary medical complications, such as renal and bladder stones, have been published, and the relationship between the occurrence of these secondary complications and subsequent rehospitalizations has not been determined. Moreover, the National Spinal Cord Injury Statistical Center

(NSCISC) data set cannot be used for this purpose, because there is no established linkage in that data set between reported occurrences of secondary complications and rehospitalizations. The purpose of this study is to provide baseline data documenting the leading causes of unplanned rehospitalizations among persons with SCI and the average costs associated with each cause, so that frequent and costly complications can be given higher priority for further study and the effectiveness of techniques to reduce the incidence of complications and hospitalizations can be assessed using rigorous cost-benefit analyses.

METHODOLOGY—The basic study design is cross-sectional with a 2-yr prospective data collection period. All persons with traumatic SCI who are currently being followed at the University of Alabama at Birmingham Spinal Cord Injury Care System (UAB-SCICS) are eligible for this study, regardless of how long ago their injury occurred.

Admission sheets for University Hospital are scanned daily to identify rehospitalizations among person with SCI. Persons returning for clinic visits and outpatient annual evaluations are asked whether they have been rehospitalized at another facility since their last contact with us. When appropriate rehospitalization is identified, medical record and billing information are obtained. ICD9CM codes are used to document the primary cause of rehospitalization. Other complications that may have contributed to the need for rehospitalization are documented as secondary causes.

The percentage of rehospitalizations, average length of stay, and charges due to each type of secondary complication will be determined. Mean length of stay and charges of each cause of rehospitalization will be compared by using Student's t test. The distribution of causes of rehospitalization will be characterized epidemiologically. The chi-square test will be used to compare the percentages of rehospitalizations due to each cause by time postinjury, age group, gender, race, education level, neurologic level of injury, degree of injury completeness, urban/rural hospital location, marital status, and presence of insurance coverage. When sample sizes for individual causes of rehospitalization permit, multiple linear regression analysis will be conducted to determine the effect of these predictor variables on length of stay and charges for rehospitalizations resulting from that cause.

PROGRESS—Data collection is underway: 446 hospitalizations have been identified and collection is complete for 369 of these hospitalizations; 58 have cost data but medical records are pending; medical records have been received for 14 hospitalizations but cost data are still pending; both medical records and cost data are pending for 5 hospitalizations.

[256] OBSTETRIC/GYNECOLOGIC COMPLICATIONS IN WOMEN WITH SPINAL CORD INJURY

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PURPOSE—Aside from the immediate and obvious consequences of spinal cord injury (SCI), many physiological systems ultimately are altered for varying periods. It is becoming increasingly evident that the reproductive axis is one such system that often is impacted by SCI. In addition to problems with menorrhea, galactorrhea, fertility, and sexual function in women after SCI, disordered hormone production in such persons could potentially result in systemic changes such as accelerated bone loss, accentuated catabolism and nitrogen imbalance, and possibly hypercholesterolemia and atherosclerosis. To date there is little information concerning these complications. The purpose of this research is to determine the changes in reproductive endocrine function both immediately following SCI and in the remainder of the first year postinjury. This research will also examine how these changes affect menstruation, ovulation, vaginal and cervical pathology, and sexual function. As it is felt that many complications of SCI, such as autonomic dysreflexia, muscle spasticity, and bladder management problems are influenced by fluctuations in the woman's hormonal cycles, these correlations will be examined as well. Possible factors that could be responsible for postinjury endocrine changes will be explored.

Objectives of this study are to document hormonal changes that influence ovulation and menstrual cycles, as well as cause complications such as hyperprolactinemia, with or without galactorrhea; to document endocrine imbalances that may occur following SCI as a result of cardiovascular instability, chest trauma, nutritional or metabolic changes, or concomitant head injury; to document the relationship between reproductive hormone levels following SCI and fertility, sexual well-being, and sexual activity; and to determine the relationship between reproductive hormone levels following SCI and complications such as autonomic dysreflexia, increased muscle spasticity, and occurrence of bladder spasms.

METHODOLOGY—The basic design of this project will be that of a prospective cohort study to assess the natural history of reproductive hormonal imbalances that cause changes in the menstrual cycle, leading to sexual dysfunction and infertility in women during the first year after SCI.

All women who agree to participate will be interviewed initially by a designated nurse/clinician, who will obtain a complete obstetrical and gynecological history. Other information collected during this interview will be first day of the last menstrual period, age, height, weight, etiology of injury, and loss of consciousness, or occurrence of closed heat trauma or chest trauma at the time of injury. Also during the initial evaluation, vaginal wall samples will be obtained by gently scraping the upper third of the lateral vaginal wall.

To evaluate postinjury reproductive endocrine status, blood sampling for hormone assays will be performed once a week for 6 wks. A single electrolyte profile, including serum sodium, chloride, potassium, blood urea nitrogen, albumin, creatinine, and glucose will be obtained on admission to the study to assess the metabolic status of each woman.

Throughout the initial inpatient stay, careful documentation of the onset, duration, and amount of flow of any menses will be recorded. Upon discharge, each woman will be given a menstrual calendar and instructed on recording this same information.

Over the 3.5-yr study, at least 28 women should be enrolled and at least 336 monthly calendars obtained.

PROGRESS—To date, entry into the study has been slow and determined by the low census of women with SCI who meet the study criteria. Four females have been initiated; one has completed the study.

[257] NATURAL HISTORY AND CLINICAL COURSE OF URINARY TRACT COMPLICATIONS IN PATIENTS WITH SPINAL CORD DYSFUNCTION

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PURPOSE—Analyzing a spectrum of urologic data acquired from a large number of persons with spinal cord injury (SCI) will help clinicians understand the natural history of the urinary tract and its complications following SCI, thus helping them select those prevention and management methods capable of assuring the most positive prognosis.

In this study, we seek to document the natural history and clinical course of urinary tract complications among persons with SCI who utilize various methods of neurogenic bladder management; answer a series of important clinical research questions that can impact future urologic management and improve the medical care and well-being of persons with SCI; and encourage the utilization of the UAB-SCI Urologic Database by other institutions, which could provide a much larger cohort of persons with SCI for future collaborative studies.

METHODOLOGY—Data are collected prospectively for each patient admitted to the UAB-Spinal Cord Injury Care System (UAB-SCICS) at admission, discharge, and annually thereafter. In addition, data have been collected retrospectively from chart reviews on 596 patients between 1970 and 1979. Since 1979, persons who were enrolled retrospectively have been followed prospectively along with the more recently injured persons. Persons constituting the prospective study group (n=1,594) were injured and admitted between 1979 and 1995. The latter group continues to grow in size; 2,190 persons have been entered into the project database. The total number of study patients with complete data at this time is 1,655, of whom 1,328 are in the prospective study.

PROGRESS—During the past year, we completed the most extensive analysis accomplished to date on the urology database. A consecutive sample of 1,114 persons with SCI, injured between 1969 and 1994, were studied. Total and individual effective renal plasma flow (ERPF) were compared to determine the effect of different bladder management methods on long-term renal function. It was concluded that renal function was adequately preserved in the great majority of persons with SCI and did not appear to be influenced to any great extent by the method of bladder management. Extensive studies were also conducted on urologic complications.

Another case study was conducted on 29 patients in the database who had died with a diagnosis of some kind of kidney disorders. An effort was made to determine any more specific causes of death, especially secondary renal amyloidosis. Almost all cases of renal involvement were secondary to some other secondary complication and were not the primary cause of death. Only one case of secondary amyloidosis was found in this database, and even the autopsy files in the pathology department were unable to identify the cases. This information supports the investigators clinical opinion that chronic pressure ulcers that cause secondary amyloidosis and renal failure, a frequent cause of death in the past, are now very rare and one of the key reasons for renal causes of death.

The database is available on computer software with quality controls that cross-check data for out of range entries and internal consistency. It has been distributed to two other SCI centers in the USA and one internationally. There is no information at this time from those facilities.

FUTURE PLANS—Because the database is getting so large, entry of new patients is being decreased and more effort given to long-term follow-up. Therefore, all females with new SCIs are entered, but only every second male with complete or sensory incomplete injuries are now entered into the database.

Another study now underway looks at the long-term outcomes and prognosis of persons with single kidneys, either due to a congenital defect, trauma at the time of injury, or urinary tract complications necessitating surgical removal of one kidney.

RECENT PUBLICATIONS FROM THIS RESEARCH

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[258] FORCE SENSORS FOR CONTROL OF POWER WHEELCHAIRS

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PURPOSE—The most common means of driving an electric powered wheelchair (PWC) is to use a joystick operated by hand or arm motion. Conventional joysticks are position-sensing devices that rely on the ability of the driver to move the stick accurately and quickly. The ability to use a joystick depends on many factors: degree of impairment, tremor, athetoid movements, balance, cognitive ability, spasticity, fatigue, and range of motion. Some people find it difficult or impossible to obtain sufficient control using existing devices.

We believe that a force-sensing joystick (FSJ) will enable people with severe physical impairments to drive PWCs. Our intent is to test the FSJ, a rigid device that senses the applied forces with a very small range of motion. Like a conventional joystick, the FSJ gives the driver two-dimensional (2-D), proportional control.

METHODOLOGY—A FSJ has been developed in our laboratories to drive a commercial PWC. A pilot study is being conducted to evaluate the feasibility of the FSJ. Subjects include a group of nonimpaired, inexperienced PWC users (controls) and a group of experienced PWC users with impairments. Subjects are asked to perform computerized tracking and real driving tasks using both the FSJ and their usual access device. Deviations from the tracks provide a measure of the tracking performance, which will be used to compare the FSJ to other access devices.

PROGRESS—A prototype FSJ has been constructed using strain gage technology. A Motorola 68HC11 microprocessor and custom electronics translate strain gage voltages into standard PWC joystick signals.

For computerized tracking, subjects sit in front of a computer with the PWC on a dynamometer that measures the speed of the PWC wheels. Interactive graphics software displays 2-D tracks and a moving icon representing motion of the wheelchair. Subjects watch the graphics while performing tracking tasks. As the subject attempts to follow the tracks, deviations from the track are measured.

For real driving tasks, subjects drive the PWC over a course marked on the floor of a gymnasium. The motion of the wheelchair on the course is recorded using a camera mounted to it. A motion analysis system processes the recordings to measure the position of the chair with respect to the course.

PRELIMINARY RESULTS—A prototype FSJ has been built to successfully drive a Quickie P300 via hand control. A group of controls has been tested on the computerized and real tracking courses, using the FSJ and a conventional joystick via hand. Preliminary analysis indicates that the FSJ provides acceptable performance for driving PWCs.

IMPLICATIONS/FUTURE PLANS—Our goal is to enable or improve powered mobility for individuals with spinal cord injuries, multiple sclerosis, cerebral palsy, Parkinson's disease, or other conditions. The next tests will include subjects with quadraplegia who are regular PWC users. The objective is enhance chin control for these individuals using force sensors.

The FSJ will be used as a clinical tool to measure the amplitude, direction, and frequency of forces applied to the FSJ by subjects with various disabilities. The forces will be evaluated in time and frequency domains to characterize the unique capabilities of each subject. The pilot data will be used to test algorithms for processing joystick signals and to develop filtering and signal conditioning algorithms. Dynamic force measurements will also provide specifications for alternative force sensors and PWC control strategies.

[259] EVALUATION OF VARIOUS FILTERING SCHEMES IN WHITENING BIOLOGICAL NOISE FOR SOMATOSENSORY EVOKED POTENTIAL DETECTION

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Sponsor: *University of New Brunswick Research Fund*

PURPOSE—Somatosensory evoked potentials (SEPs) contain important physiological information, and have become a widely accepted and employed monitoring technique during back surgery. However, as surface-recorded SEPs have very poor signal-to-noise ratios (SNR), signal processing is required to acquire usable information from the recorded data. Although coherent ensemble averaging is the conventional method of improving the SNR, it consumes a significant amount of time. As a result, alternative techniques, such as matched filters, have been investigated in an attempt to reduce the number of averages needed for detection. A matched filter is the optimum technique for detecting a known signal buried in additive white noise. The effect of the non-white biological interference afflicting SEP measurements is investigated, and various whitening filter schemes are examined in an attempt to improve matched filter performance. Emphasis is placed on determining a satisfactory linear adaptive whitening filter routine.

METHODOLOGY—Three linear adaptive algorithms—sign adaptive, recursive least-squares, and least-mean square—are evaluated, as are a brute force approach and a nonlinear neural-network technique. The LMS algorithm is found to be best suited for the desired implementation.

RESULTS—By applying signal whitening to surface recorded evoked potentials substantial improvement was made over earlier work. This was especially noticeable at high spinal levels where the contributing noise is contaminated with cardiac and respiratory activity. In this work, the ambiguity, in which peak corresponds, to the SEP has been resolved.

With no whitening, the output from the matched filter shows multiple peaks; with whitening, only a single peak is resolved with zero latency. Consequently, this is ideal for an amplitude detection scheme.

B. Treatment and Rehabilitation

[260] THE EFFECTS OF SPINAL INSTRUMENTATION

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PURPOSE—This project seeks to determine the static and dynamic function of multisegmental spines in human and goat cadaveric models. Flexibility properties of the multisegmental spine will be compared to previously reported single segment studies. Changes in flexibility behavior following cutting soft tissue structures and following the application of spinal instrumentation will be studied.

METHODOLOGY—The biomechanical behavior of cadaveric goat and human spine specimens will be analyzed by stereophotogrammetry when loaded under pure moments under various conditions. Unique to this study, the moments will be applied dynamically. Once control data are obtained, partially destructive studies will be performed. These studies will be followed by the application of spinal instrumentation on the multisegmental spine specimen.

PRELIMINARY RESULTS—A biomechanical study of reconstruction following multilevel corpectomy using dynamically applied moments has been completed and is being prepared for publication. An improved method for applying the moments has been developed and validated.

FUTURE PLANS—Testing of the goat and human cadaveric spine models is anticipated to be complete in 1998 with data analysis and presentations to follow.

[261] FUNCTIONAL RESTORATION OF GRASP IN QUADRIPLEGIA

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B898-2RA)*

PURPOSE—Our overall objective is to improve functional grasping in persons with quadriplegia by providing them with the biomechanical ability to grasp objects. Reconstructive surgeries, including tendon transfers, are commonly performed in these persons to restore partial grasping function, but uncertainty in the functional outcome of new surgical approaches hinders our ability to achieve improvements in their treatment.

METHODOLOGY—A biomechanical model of the hand musculotendinoskeletal system will be developed to provide surgeons with an *in vitro* testbed for improving existing techniques, or trying new techniques, and predicting functional outcomes. A hand model would be, by definition, an encyclopedic knowledge-base relating musculoskeletal anatomy to hand function. Such a model would allow surgeons to determine the precise musculotendinoskeletal parameters to which the functional outcome of a surgical or rehabilitation procedure is most sensitive. Thus, those aspects of the surgical procedure needing close clinical scrutiny could be identified. A model of the index finger and thumb will be the focus because of their importance to grasping (e.g., tip and key pinch) and because of the anatomic similarity between the index finger and the other fingers. The ability of the index finger and the thumb to exert maximum grasping (pinch) forces will be emphasized because they specify the biomechanical limit of grasping performance.

PROGRESS—A computer-implemented musculotendinoskeletal model of the index finger has been developed. Finger tip forces were recorded in five directions as subjects pressed as hard as possible against a low frictional surface with the finger in three different postures. EMGs from all seven index finger muscles were recorded with intramuscular electrodes. Analysis of coordination of force generation in three directions was emphasized.

RESULTS—In the palmar direction, all muscles but palmar interosseus were highly excited. In the distal direction, the interossei were excited the most, the lumbrical and flexor muscles next most, and the extensor muscles the least. In the lateral direction, the palmar interosseus and extensor muscles were excited the most, the dorsal interosseus the next most, and the lumbrical and flexor muscles the least. The 3-D, seven-muscle model of the index-finger was found to reproduce the force and coordination observed during the generation of palmar and distal forces. However, the interossei co-excitation observed in lateral force generation could not be reproduced, perhaps because the subjects used an injury prevention coordination strategy, which was not included in the model.

FUTURE PLANS—We will develop a musculotendinoskeletal model of the thumb and test its validity by recording forces produced by the thumb and intramuscular EMGs consonant with force generation, again with subjects instructed to press as hard as possible against a low frictional surface with the thumb in different postures. With a model of the finger and thumb then developed, the complex biomechanical and neural interactions that make grasping possible can be analyzed.

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[262] SKELETAL CHANGES AFTER SPINAL CORD INJURY AND CAST IMMOBILIZATION

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B802-RA); NASA Ames Research Center, Mountain View, CA 94035; National Institutes of Health, Bethesda, MD 20892*

PURPOSE—The objective of this study is to use high resolution Quantitative Computed Tomography (QCT) imaging of the calcanues in conjunction with computer modeling to develop a new noninvasive, human model for the study of functional adaptation of bone tissue. By charting the time course of bone loss or gain within small volume elements of bone in subjects with spinal cord injuries or immobilized by fracture casts, we will investigate the nature of bone remodeling and the related issue of reversibility of changes in bone density and structure in cancellous and cortical bone. This study will provide important new insights for better understanding the basic mechanisms of bone adaptation. These insights, in turn, should suggest new and improved clinical treatment strategies.

METHODOLOGY—This study uses a combined experimental and computational approach to investigate skeletal changes with disuse. Our study involves the use of QCT and dual-energy, x-ray absorptiometry (DXA) to measure serial changes in bone mass. Four specific tasks will be accomplished:

1. registration of serial CT scans of the calcaneus in patients;
2. accurate and precise determination of bone density in the calcaneus;

3. determination of the local bone remodeling rate; and
4. comparison of measured adaptation rates with computer predictions.

PROGRESS—The registration task has been accomplished in collaboration with investigators in the Department of Radiology at Stanford University. The second task necessitates the development of a new technique to eliminate or minimize beam hardening from the CT data sets. The third task will be accomplished by scanning subjects using high speed CT scanner and the above QCT techniques. In the computational component of the study we will use 2- and 3-D finite element models of the calcaneus to simulate skeletal adaptation using a bone remodeling theory previously developed in our laboratory.

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[263] CLINICAL TRIAL OF ARTIFICIAL PERIPHERAL NERVE GRAFT

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B588-3RA)*

PURPOSE—The recovering damaged nerve normally has a high population of Schwann cells that made up the myelin sheaths of axons prior to injury. These cells secrete growth factors and repair the extracellular matrix in preparation for the extension of regenerating axons into the damaged region. This project is based on replacing the Schwann cells in an otherwise acellular artificial nerve graft (ANG) as a substitute for an autograft taken from elsewhere in the subject's body. The latest ANG formulation is to be tested in lieu of an autograft in persons having trauma to the hand or arm, or to replace sural nerves removed for autografting.

METHODOLOGY—Preparation of the ANG essentially consists of repolymerization of solubilized collagen fibers with added cultured Schwann cells and insertion into a biodegradable conduit. Type I collagen is preferred because it is readily available, relatively inexpensive, and its properties are reasonably well understood. The matrix or conduit walls could include regeneration-promoting agents such as nerve growth factor. The conduit limits penetration of inflammatory cells into the region of axonal regrowth, as well as facilitating microsurgical reanastomosis with the proximal and distal ends of the nerve.

PROGRESS—In a series of animal implantations, a graft formulation has been achieved having the same functional recovery as an autograft. Based on this result, a limited clinical trial (up to 10 persons per year) has been approved. A subject's Schwann cells will be obtained from remnants of the damaged nerve, or from a short (5 mm) donor nerve biopsy that can later be repaired with an ANG. A preclinical phase is underway, in which culture methods for adult human Schwann cells are being optimized. Potentially immunoreactive components are being deleted from the fabrication process, long (30 mm) grafts are being tested for efficacy and durability in a rat model, and clinical sensorimotor measurements for functional recovery are being refined. In the latter activity, former subjects having had nerve repair are being recruited for a comparative database. A collaboration has been established with the Medical Photonics branch of Lawrence Livermore National laboratory to explore laser-assisted measurement of neurally mediated changes in skin blood flow.

FUTURE PLANS—There is potential for tissue-engineered grafts to bridge traumatic defects in the central nervous system. Our laboratory is collaborating with researchers at Hines VA Medical Center by fabricating grafts for testing Schwann cell-seeded implants in spinal cord injuries in rats.

[264] HIGH-FREQUENCY MAGNETIC STIMULATION OF THE BLADDER AND BOWEL

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420*
(Project #B803-2RA)

PURPOSE—The purpose of this research was to determine the effects of high-frequency magnetic stimulation (HFMS) of the sacral nerves on bladder and rectal pressures (BP and RP) in persons with spinal cord injury (SCI), and to optimize the magnetic stimulation parameters to obtain functional micturition and defecation.

METHODOLOGY—Eight persons with SCI (C4–T12) were recruited for the 2-day protocol. In day one (Bladder day), each received a screening history and physical examination, bulbocavernosus reflex latency, as well as a full urodynamic study. This was followed by magnetic stimulation of the bladder using a Cadwell stimulator, with a 9-cm magnetic coil placed near the L2–L4 vertebrae while measuring BP and RP. The frequency and intensity stimulation parameters were initially fixed at 20 Hz and 70 percent of maximum while changing the placement of the magnetic coil to optimize the focus of stimulation. Once the optimal placement was determined, the parameters were systematically varied to generate frequency and intensity profiles. Finally, functional micturation was attempted before the end of the bladder protocol. The second day (Bowel day) consisted of a full rectodynamic study, and magnetic stimulation of the bowel. Functional defecation was attempted at the end of the bowel day. Laboratory tests, including a set of Chem 20, CBC with differentials, PT, PTT, UA, and urine cultures, were performed both before and after the experiment.

PROGRESS—We have demonstrated that HFMS of the sacral nerves was effective in elevating bladder and rectal pressures. The optimal stimulation parameters were 20 Hz frequency and 70 percent of maximal power, which provided adequate nerve stimulation in most subjects. We were able to observe functional magnetic micturation in most subjects; defecation was more difficult to achieve but was observed in some cases.

RESULTS—To date, 22 subjects have participated in the bladder HFMS protocol. With sacral nerve root stimulation, the mean increase in bladder pressure of 24.4±4.88 cm of H_2O; with suprapubic stimulation, the mean change was 16.5±4.4 cm H_2O. The change in bladder pressure was significantly greater with sacral nerve root stimulation ($p<0.01$). Micturation was observed in 17 of the 22 subjects with either sacral nerve root or suprapubic stimulation. The frequency and intensity profiles showed that a frequency of 20 Hz and 70 percent of maximum generated adequate pressure changes in most subjects, although higher intensities and frequencies could generate higher bladder and rectal pressures. Either suprapubic or lumbosacral stimulation would result in urination. On the second (bowel) day, rectodynamic studies revealed an average rectal capacity of 310±30 ml, and peak defecating pressure of 85±13.3 cm H_2O. The mean rise in rectal pressure after HFMS was 22.8±6.05 cm of H_2O. Of the 13 subjects who completed the bowel protocol, we observed defecation in two cases.

FUTURE PLANS—We plan to investigate whether the production of micturation by HFMS can be improved by conditioning the bladder muscle; we shall further evaluate the effectiveness of HFMS in producing defecation and whether bowel motility is modified by HFMS by evaluating colonic transit time.

RECENT PUBLICATIONS FROM THIS RESEARCH

Functional magnetic defecation in paraplegia. Lin VW, Wolfe V, Perkash I. J Spinal Cord Med 1995;18(4):263–4.

Functional magnetic micturition in spinal cord injured patients. Lin VW, Wolfe V, Prionas S, Perkash I. Archives of PM&R, 1995;76(11):1039–40.

[265] TREATMENT OF SCIATIC NERVE INJURY WITH GONADAL STEROIDS

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PURPOSE—Gonadal steroids are neurotrophic agents capable of modulating many aspects of neuronal growth and function, and thus have therapeutic potential in the treatment of nerve injuries involving lower motor neurons. The key question that is being addressed is the following: Will systemic administration of the gonadal steroid, testosterone propionate (TP), augment the regenerative properties of spinal motor neurons, analogous to the effects of steroid on cranial motor neurons? The goal of this research is to determine if TP can be used as a therapeutic agent in spinal cord injuries.

METHODOLOGY—The experimental approach that is being used ranges from functional (for the determination of rehabilitation potential) to molecular (for the determination of mechanism). The long-term goal of this research is to determine the therapeutic potential of gonadal steroids in spinal motor neuron regeneration in animal models and subsequently extrapolate this information to human peripheral nerve and spinal cord injury situations. There are four sets of experiments. The experimental model is the rat sciatic motor neuron. The sciatic nerve is crushed at the level of sciatic notch in castrated male rats, with half of the animals receiving subcutaneous implants of TP and the other half sham implanted at the time of injury. Functional assessment of lower limb movement and locomotor behavior has been done. The Sciatic Functional Index (SFI), a quantitative measure of locomotion, was used to analyze footprints from 1–7 weeks postoperative. Molecular analysis of the effects of TP directly on injured sciatic motor neurons has been initiated using *in situ* hyrbridization with specific probes.

PROGRESS—Currently, details of the behavioral and molecular analyses have been accumulated in pilot studies. The appropriate behavioral tests have been identified and the conditions for use of DNA probes in the *in situ* hybridization experiments established. This year, behavioral experiments to test the ability of testosterone to accelerate recovery of function were accomplished. In this study, we asked the following question: Will TP treatment accelerate recovery from lower limb paralysis following sciatic nerve crush in the rat? After footprint analysis, we found that at 1–3 wks post-op, the SFI of the TP-treated and control groups were not significantly different. Between 3–4 wks post-op, the TP-treated group had a significantly higher SFI score than controls, indicating a greater degree of functional recovery. At these timepoints, the differences are attributable to the foot print or paw length components of the SFI. These components are associated with calf muscle reinnervation, rather than the toe-spreading component associated with intrinsic foot muscle reinnervation. Beyond 5 wks post-op, there were no differences in the SFI scores. The results indicate that, as with facial nerve regeneration in the hamster, testosterone accelerates functional recovery from lower limb paralysis following sciatic nerve injury in the rat.

FUTURE PLANS—Currently we are preparing for *in situ* hybridization experiments that will test the hypothesis whether testosterone accelerates the rate of rat sciatic nerve regeneration through differential regulation of cytoskeletal gene expression following injury. Specifically, we wish to address the following questions. Which cytoskeletal genes are differentially regulated by testosterone following crush/axotomy? Does testosterone accelerate the onset of crush/axotomy-induced changes in the expression of these genes? We also plan to use the *in situ* technique to look at the effects of testosterone on the ribosomal RNA gene after injury.

[266] GONADAL STEROIDS AS REHABILITATIVE AGENTS AFTER PARTIAL SPINAL CORD INJURY

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PURPOSE—Gonadal steroids have been shown to have profound neurotrophic effects on injured peripheral motoneurons containing the androgen receptor, resulting in an acceleration of the rate of regeneration. Many of these effects are found on a molecular level, with steroids being able to directly alter the expression of many genes. Many populations of central neurons, including upper motoneurons, express the androgen receptor. Could gonadal steroids influence the expression of important repair-associated genes in these upper motoneurons after an injury as they are capable of doing in peripheral motoneurons? The objective of the proposed study is to test the hypothesis that treatment of central motoneurons having a limited capacity to regenerate with testosterone propionate (TP) will produce a reparative response to injury analogous to that observed in peripheral motoneurons capable of successful regeneration. The success of these studies may lead to potential therapeutic uses of gonadal steroids in treatment of head trauma and spinal cord injury.

METHODOLOGY—The experimental model that will be used involves a C7–T1 spinal cord hemisection of gonadectomized adult male hamsters. The hemisection model affords a method of directly observing the effects of injury and TP administration on one tract of an upper motor neuron population, namely the rubrospinal tract, while leaving the contralateral tract intact for a direct nuclear comparison. Using an *in situ* hybridization technique, relative levels of both product 28S rRNA and precursor 45S rRNA, important components of a cell's protein manufacturing capability, will be examined in the cell bodies of the red nucleus as early as 6 hrs postinjury. Additionally, relative levels of mRNA coding for important regeneration-relevant proteins, including cytoskeletal proteins, GAP-43, and GFAP, will also be examined in the red nucleus using *in situ* hybridization from 2 days postinjury (dpo) to 21 dpo.

PROGRESS—*In situ* hybridization studies examining rRNA levels in injured rubrospinal neurons have just recently been initiated. Initial pilot studies have been completed for *in situ* hybridization examination of rRNA, confirming appropriate probes and conditions for the technique. Additionally, characterization of the red nucleus in hamster, including mapping studies and cell quantification, has been completed prior to the initiation of any molecular-based studies. These anatomical studies have helped in isolating those spinal projecting neurons in the red nucleus which will exclusively be used for studying the effect of a spinal cord injury, and have also proven the comparability of red nuclei between different animals for the purpose of determining effects in an accurate manner.

FUTURE PLANS—*In situ* hybridization experiments for regeneration-relevant mRNAs will immediately follow the conclusion of the rRNA studies. Additionally, Western blotting and immunohistochemistry will be used to examine the relative levels of cytoskeletal, GAP-43, and GFAP proteins that are altered following an injury and TP treatment. This will determine whether changes in mRNA levels in injured rubrospinal neurons can indeed be equated into changes in functional protein levels, which would be necessary for an enhanced repair response.

[267] FECAL INCONTINENCE TREATMENT IN SCI PATIENTS: A PILOT STUDY

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PURPOSE—The objectives of this study are to determine the optimum stimulation parameters to manage fecal incontinence in subjects with SCI; to evaluate anorectal function using manometry in these subjects; and to determine whether there are any other benefits associated with external anal sphincter stimulation.

METHODSEight nonimpaired male controls were recruited through physician recommendations. Informed consent was obtained from all participants prior to the study. The protocol was approved by the Hines VA Human Studies Subcommittee. Anorectal manometry was carried out at the bedside before, during, and after perianal stimulation. A medically approved sterile, water filled, balloon catheter was attached to a battery operated strip chart recorder via a pressure transducer. The balloon was placed into the rectum for baseline rectal pressures and then pulled into the anal canal for baseline anal pressures. For perianal stimulation, two surface electrodes were placed externally adjacent to the anal opening either laterally or along the midline. Changes in either rectal or anal pressures were recorded as the stimulating current was slowly increased.

PROGRESS—Perianal surface stimulation was effective at increasing anal pressures. This stimulation increased anal pressures up to ten times those recorded with coughing, bearing down, or manually pushing on the perineum.

RESULTS—Of the eight subjects enrolled, five underwent perianal stimulation. Stimulation parameters consisted of a pulse duration of 300 μs, stimulating frequency of 35 pps, and a current sweep of 0-100 mA. Four of these five had increases in anal pressures with electrical stimulation. The average increase in anal pressure was 71.38±44.04 at an average current of 81.25±14.36. There was no effect on rectal pressures with electrical stimulation. Lateral electrode placement was evaluated in one subject and found to be more effective than the midline orientation. One subject indicated that the device was effective at reducing his rectal pain.

FUTURE PLANS—We shall modify our approach to include a combination intra-anal electrode and balloon catheter assembly.

RECENT PUBLICATIONS FROM THIS RESEARCH

Perianal electrical stimulation increases anal pressure. Chintam R, Riedy L. Am Parapleg Soc. In press.

[268] PROPHYLACTIC MONITORING OF BLADDER PRESSURE AND VOLUME

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PURPOSE—Individuals with spinal cord injury (SCI) and multiple sclerosis (MS) have a high incidence of urinary incontinence, kidney dysfunction, and other urological pathologies. To aid in the early detection and possibly the prevention of these pathologies, we evaluated a simple home-use pressure gauge with tubes to measure bladder pressure and urine volume as an adjunct to intermittent self-catheterization (IC) in individuals with SCI and MS.

METHODOLOGY—The home-monitoring pressure gauges and clinical urodynamic equipment were calibrated with a standard water column to read the same pressure within 1 cm of water. Two different gauges were used. The first was a digital gauge with a zero adjustment, a highly accurate pressure reading and a small volume displacement for pressure recording. However, subjects found it hard to read. The second home gauge was a mechanical bellows type with pressure indicated in cm H_2O on the dial face. We currently use this second gauge. Initial clinical urodynamic evaluation, including bladder filling, or cystometrogram (CMG), was conducted with simultaneous recording of pressure using the clinical equipment and the home gauge.

For home use, subjects were given instructions on connecting a sterile tube from the pressure gauge to their catheter for IC. They were asked to record their bladder pressure when they initially catheterized, a full bladder pressure, and a nearly empty bladder pressure as a measure of abdominal pressure. They were asked to conduct pressure and volume recording on a weekly basis, more often if they were having a urological problem, and to conduct the recording for 1 yr. An estimate of detrusor pressure, the pressure due to the bladder wall, was obtained by subtracting a nearly empty bladder pressure from the full bladder pressure obtained upon initial catheterization.

RESULTS—Eight subjects have entered this study, seven with SCI and one with MS. The average age was 46.4±9.3 years. All the SCI subjects had upper motor neuron lesions. All subjects were on IC for bladder emptying, and home monitoring of bladder pressure was conducted without adverse effects. In the urodynamic clinic, the home pressure gauge was found to record the same pressures obtained with standard clinical urodynamic equipment within 3 cm H_2O.

Although home monitoring was proposed for 1 yr, all of the subjects withdrew sooner. Five of eight recorded an average of 27±21 home pressure recordings over 3.5±2.9 months. Three did not record any home data. Reasons for withdrawing included too busy, personal problems, or procedures were too bothersome. Two subjects also stated that they did not think the pressure recordings were helping them.

Subjects on IC were able to conduct home monitoring of bladder pressure and volume. For the majority, the bladder capacities between CMG and home records could not be compared because the CMG was stopped at a volume of 500 ml. At each volume of overlap, CMG vesical pressures were compared to home full bladder pressures; CMG rectal pressures were compared to home empty bladder pressures; and CMG detrusor pressures were compared to home detrusor pressures. When the results from five subjects were combined and mormalized to the percent pressure at maximal CMG capacity, the home full- and nearly empty bladder pressures were significantly lower than the CMG bladder and rectal pressures, respectively. In contrast, there was no significant difference between the home estimate of detrusor pressure and CMG detrusor pressures.

FUTURE PLANS—A CMG recording is the gold standard for determination of bladder function in subjects with SCI. Home monitoring of bladder pressure cannot substitute for clinical CMG measurement. However, CMGs are time-consuming and expensive and may not be performed as often as are needed. We suggest that, in subjects performing intermittent catheterization to empty the bladder, frequent home monitoring of bladder pressure could supplement CMG recordings and would enable early identification of high detrusor pressures. Home monitoring could be an effective adjunct to clinical CMG studies.

RECENT PUBLICATIONS FROM THIS RESEARCH

Home monitoring of bladder pressure in individuals with neurogenic bladder. Damaser MS, Walter JS, Wheeler JS, Inman SR, Chintam R. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press, 1997. p. 97–9.

A bladder-pressure home-monitoring device for patients conducting intermittent catheterization. Walter JS, Markley JC, Wheeler JS, et al. J Urol 1996;155(Suppl):383A.

[269] QUANTITATIVE STUDY AND AUGMENTATION OF COUGH IN PERSONS WITH SPINAL CORD INJURY

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PURPOSE—Pulmonary complications are one of the major contributors to morbidity and mortality of persons with spinal cord injuries (SCI). The purpose of this study is to improve electrically stimulated cough in individuals with SCI; to establish a quantitative measure of the quality of cough in individuals with SCI as a function of the characteristics of injury, anthropometric measurements, and standard measures of pulmonary function; and to classify individuals at risk of pulmonary complications based on cough ability, suggesting those who might benefit from electrically stimulated cough.

METHODOLOGY—Three hypotheses will be tested. I: whether the existing scheme of electrically stimulated cough production can be improved to obtain cough peak flow rates (CPFR) of at least 350 L·min−1, by triggering the cough on sensing an event related to glottis closure. In a random order, CPFR will be measured in 25 individuals during electrically stimulated cough with and without the new triggering method. A paired t-test will be used to evaluate differences in CPFR between the original and new triggering methods.

II: whether efficacy of volitional cough in a given individual (as measured by CPFR) is related primarily to level of injury, sex, and the volume of air exhaled in the first second of a forced exhalation (FEV1). Unassisted CPFR will be measured in 250 to 300 individuals with SCI. Participants will complete a pulmonary function test and anthropometric measurements. Multiple linear regression analysis with CPFR as the dependent variable will be performed. The hypothesis will be accepted if level of injury, sex, and FEV1 are the only variables retained.

III: whether CPFR can be used to classify subjects as having or not having had pulmonary complications in the past 2 yrs. Using the data obtained in II, and evidence from medical records, subjects will be divided into two groups: pulmonary complications and no pulmonary complications. The expectation that CPFR is normally distributed in each group (as suggested by preliminary data) will be verified. Employing receiver-operator characteristic curves and using CPFR as a predictor, the sensitivity and specificity for prediction of pulmonary complications will be calculated.

PROGRESS—Over the first 8 mo of the study, CPFRs were collected from 64 individuals with SCI between C5–L5. Based on subjective report of complications, individuals without complications had a mean CPFR of 334 L·min−1 (sd=141); individuals with complications had CPFR of 220 L·min−1 (sd=128). Medical records are now being reviewed to precisely determine presence or absence of pulmonary complications. Engineering of the electrical stimulation system for augmentation of cough is in progress. A computer monitors airflow from a pneumotachograph, continuously analyzing the breathing pattern. When a cough is desired, as indicated by a push button, the computer begins searching for a deep inspiration, followed by the zero air flow that indicates glottis closure. Abdominal stimulation then can be precisely triggered relative to glottis closure. An attempt will be made to determine if CPFR can be increased based on timing of delivery of stimulation.

IMPLICATIONS—Independence from care givers is nearly always a hallmark of effective rehabilitation in SCI. The longer-term goals are to confer this independence upon individuals with SCI with respect to cough, and to lower the incidence of pulmonary complications.

[270] CORTICAL SENSORIMOTOR REORGANIZATION IN SPINAL CORD INJURY

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PURPOSE—We have determined it is feasible to detect reorganization of motor control in the cerebral cortex following spinal cord injury (SCI) and have now characterized that reorganization.

METHODOLOGY—We are applying a new technology of 128-electrode high resolution electroencephalography (EEG) to determine the topography of motor representation changes by mapping electrical potential distributions (MPs) with actual and attempted movements of the fingers and toes in nonimpaired controls and SCI subjects. Movements are self paced if subjects are able, or visually cued if only attempted. The generators of the potentials are localized by dipole source analysis, utilizing subject-specific magnetic resonance images (MRI) in a realistic head model. The dipoles and current density fields are co-registered with the subjects' MRI images.

PROGRESS—We have studied 12 subjects and 15 controls.

RESULTS—EEG recordings in seven persons with quadriparetia (C2-3 through C7-T1) during finger movement showed MPs displaced posteriorly in all. One of five persons with paraplegia had a posterior location. Dipole Source analyses suggested an origin in the somatosensory cortex.

FUTURE PLANS—We must now initiate our studies as soon as subjects are admitted for rehabilitation and follow them with EEG's and appropriate scales to measure outcome. In this way we should be able to establish a relationship between posterior reorganization and clinical course and prognosis. If detrimental to recovery, it may be desirable to attempt clinical trials at prevention.

RECENT PUBLICATIONS FROM THIS RESEARCH

An electroencephalographic study of imagined movement. Green JB, Bialy Y, Sora E, Thatcher RW. Arch Phys Med and Rehab 1997;78:578–81.

The spatial distribution of the cortical motor potentials and generators change after spinal cord injury. Green JB, Bialy Y, Sora E, Ricamato A, Thatcher RW. Neuroimage 1997;5(Suppl):5264.

An electroencephalographic study of cerebral reorganization after spinal cord injury. Green JB, Thatcher RW, Sora E, Bialy Y, Ricamato A. Neurology 1996;48(Suppl):6–49.

[271] ADVANCED TECHNOLOGY NEURAL INFORMATION SENSORS FOR PROSTHETIC CONTROL BY QUADRIPLEGICS

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PURPOSE—The objective of this research is to develop technology capable of transducing neural information from the motor cortex, so that persons with quadriplegia can control of FES systems via chronic implantation. Currently, wiring from the skull to the brain surface causes relative motion of electrodes with respect to the brain. Our specific aim is to develop the integrated circuit telemetry techniques and implant structure that will provide a wireless, mechanically stable neural interface for many years. The key question to be addressed is: what would be a reasonable design for a chronic neural information sensor that could be chronically implanted for the rehabilitation of the person with SCI?

PROGRESS—Atraumatic electrode fabrication techniques were developed and acute trauma due to insertion was evaluated. Long-term studies indicated excellent neuron survival within a few microns of the shafts. An electrically isolated, low-noise recording system was constructed and used to document cortical signal characteristics. A low-noise test system for characterization of integrated circuit transistors was designed, constructed, and used to develop advanced mathematical noise models for use in design of optimized neural encoders. Optical telemetry techniques for data and power were developed. Two integrated circuit chips were fabricated for analysis of basic design issues, low-noise pre-amplifiers, and transmitter modules. The second circuit also included a functional 8-channel neural waveform encoder/transmitter that consumed only 31 μW. With minor modifications, this design will serve as the basis for a free-floating, implantable, 8-channel multiplexed neural waveform transmitter. Instrumentation was developed for detecting the optical data pulses. Efficient data decoders were developed for acquiring the neural information. An animal model using visual evoked potentials (VEPs) suitable for studying chronic neural signal transmitters was developed. Techniques for processing and interpreting VEPs to identify the retinal representation of the implanted microelectrodes were developed. Prototype circuits were developed and implanted subcutaneously in two animals.

RESULTS—An assembly error caused the encapsulation used for the first implant to fail after a few weeks. The second implant has transmitted neural signals from the visual cortex for over 1 yr and has been used extensively to test new instrumentation and software. A technique for generating contour plots of activation as a function of time post-stimulus was developed and used to locate the area of the retina associated with the implanted microelectrodes. The area associated with the implant can then be focally driven to elicit single unit activity that can be followed over time. Thus far, the characteristics of the VEPs have been remarkably similar month to month.

FUTURE PLANS—Immediate plans are to publish results thus far and finish fabrication and testing of the multiplexed neural waveform transmitter. Biocompatibility issues should continue to be studied as the new technology is refined. In particular, quantitative histological studies should be conducted once free-floating implants are available. Free-floating neural signal transmitters should be constructed and tested in a dog model where subdural space and brain movements are larger. Action potential encoders should be developed to allow transmission of many more channels of information than can be accomplished with the current analog encoding approach. Free-floating devices should evaluated for long-term damage and function in dogs. Experiments to determine whether motor control information can be extracted should be carried out in dogs with free-floating multichannel transmitters using behavioral techniques. A limited clinical trial should then be designed to evaluate use of the technology for extraction of motor control commands from the motor cortex for prosthetic control.

RECENT PUBLICATIONS FROM THIS RESEARCH

Low power, low noise design for implantable biomedical microelectronics. Larson BC. In: Health sciences and technology. Cambridge, MA: MIT; 1996. p. 87.

[272] A BIODEGRADABLE DEVICE FOR PERIPHERAL NERVE REPAIR

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PURPOSE—The overall goal of this research program is to increase the degree of functional recovery following nerve injury, using the nonhuman primate hand as a model system.

The balance and coordination between the magnitude of grip force and weight of an object (or load force) is critical for manual manipulation of objects. Too weak a grip force may cause slippage, while excessive grip force may damage an object and/or cause unnecessary muscle fatigue. The use of excessive grip force imposes a greater resistance against which antagonist muscles must work. This may make it more difficult to further manipulate an object, as would normally be accomplished by the application of additional forces superimposed upon the basic grip force. Rapid adjustments to unanticipated or inaccurately predicted changes in load force is critical both to the effective manipulation of objects in the environment (such as a screwdriver or wrench), and to the safety of the individual (as in the manipulation of power tools). Paramount to these movements in normal functioning of the hand is the ability to exert voluntary motor control.

We have compelling evidence that application of nerve growth factors (NGF and aFGF) to a nerve repair site in rodents significantly increases the proportion of motor axons that correctly regenerate into a distal motor nerve branch rather than an inappropriate sensory nerve branch. Data from related primate studies consist of electrophysiological and histological assessments of regeneration, and also show a tendency for motor axons to reinnervate a terminal motor nerve pathway. However, this type of data can only provide correlates of functional recovery: we have no data on the actual recovery of hand function in the awake, behaving animal. This study will attempt to answer the very complex yet seemingly simple question, ''But, how well can the animal use its hand?''

METHODOLOGY—We will compare the rate and extent of recovery of normal hand function following surgical repair of the median nerve with and without the addition of growth factors. Monkeys will be trained to grasp a manipulandum using the ''key grip'' (the grip one would employ when using a key), lift it 1 to 2 cm, and briefly hold it suspended in order to obtain a reward. The device will monitor the applied grip force, load force, and elevation throughout each trial.

The ability to scale grip force reflexively in response to sensory input will be assessed by altering the manipulandum's surface texture, varying the load force required to suspend the device, and by simulating slippage by exerting a sudden downward force on the suspended manipulandum during the hold phase of the task (smooth objects, heavy objects, and objects that are slipping are normally grasped more firmly than their counterparts). Since the ability to scale grip force to surface texture, load force, and slippage depends upon sensory feedback mediated in part by the median nerve, it will be of interest to determine whether the addition of growth factors may be of benefit to these abilities.

In a second task designed to assess voluntary motor control, the monkeys will be required to adjust their grip force in response to visual cues presented on a computer monitor. We predict that the enhanced motor reinnervation induced by the growth factors will significantly enhance the recovery of the ability to voluntarily scale grip force in response to a visual stimulus.

PROGRESS—Four monkeys are currently engaged in behavioral training prior to surgical transection and repair of the median nerve.

FUTURE PLANS—Future work will be directed toward developing the technique as a adjunct to standard clinical nerve repair.

[273] ACUTE EFFECTS OF SCI ON SPERM FUNCTION

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PURPOSE—Infertility is a common problem in men following spinal cord injury (SCI). This is due to ejaculatory dysfunction and poor semen quality. With advances in techniques of electroejaculation, semen may be obtained in approximately 90 percent of men with SCI. Unfortunately, semen parameters, particularly sperm motility, are usually of poor quality following SCI. An acute decline in semen quality has been documented to occur shortly after SCI both in humans and in an SCI animal model. Advances in assisted reproductive technologies such as *in vitro* fertilization have allowed some men to father children. However, these techniques are extremely expensive and often have limited availability. The purpose of this project is to identify the causes of this decline in sperm quality and to identify treatment strategies that may help to prevent this decline.

METHODOLOGY—We are studying both an SCI animal model (Sprague Dawley rat) and men with recent SCI. Animal studies involve mature rats with a T9 transection and sham-operated controls. Drug studies investigating the possible impact of medications, specifically verpamil and L arginine on preventing decline in sperm motility have also been evaluated in our animal model. Studies are underway evaluating differences in nitric oxide (NO) in SCI and non-SCI animals. Scrotal temperature studies in men with SCI have just begun. Since electroejaculation has been found to be unreliable in obtaining ejaculates in SCI rats, sperm is obtained by epididymal puncture. Vesicostomy rather than around-the-clock crede of the rat bladders following SCI has also been evaluated. Possible use of a new SCI animal model (guinea pig), which will allow repeated electroejaculation rather than animal sacrifice at specific time intervals, has been evaluated.

PROGRESS—Previous testicular blood-flow studies have revealed a persistent decrease in testicular blood flow in the SCI animals compared to sham controls at 2 and 4 weeks post SCI. A decline in semen quality shortly after SCI may be prevented by maintaining normal testicular blood flow after SCI. Our study has evaluated several medications to maintain testicular blood flow. Pilot studies have shown improvement in semen quality with L arginine but not verpamil when SCI animals were treated and compared to non-treated SCI animals. Since L arginine is a mediator of NO, studies to evaluate testicular NO are underway. While there has been difficulty obtaining ejaculates using electroejaculation in the rat model, there was a high success rate (70 percent) in obtaining ejaculates in the guinea pig SCI animal model. Unfortunately, there was an increased death rate in rats with vesicostomy and guinea pigs with SCI. Therefore, we have made no changes in our SCI animal model.

FUTURE PLANS—Work will continue to focus on medical interventions with a particular emphasis on L-arginine and NO. Studies are also going to begin to evaluate the impact of SCI on testicular temperature regulation after SCI, in both the animal and human model.

[274] NEUROPROSTHETIC CONTROL OF BLADDER AND BOWEL IN SPINAL CORD INJURY PATIENTS

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PURPOSE—Our research goal is to evaluate an electrical stimulation technique for improving bladder and bowel function after spinal cord injury (SCI).

METHODOLOGY—Finetech-Brindley stimulators were implanted surgically in 20 subjects at least 1 yr after clinically complete SCI. All except two also underwent posterior sacral rhizotomy. Subjects of either gender were selected on the basis of having significant bladder complications, such as chronic or recurrent infection or reflex incontinence and intolerance of anticholinergic medication. Clinical and laboratory investigations were used to assess bladder emptying, infection, urodynamic parameters, vesico-ureteric reflux, and hydronephrosis. Colorectal studies were used to assess defecation and colorectal motility, and new electrical stimulation techniques were tested in an attempt to improve further the restoration of bladder and bowel function. Each subject was used as his or her own control, comparing measurements before and after the procedure.

PROGRESS—All implants are working well and all except one are in daily use at home for bladder emptying. The study, begun at the VA Medical Center in Cleveland, has been extended to the VA Medical Centers in the Bronx and San Diego, as described below.

RESULTS—Fifteen males and 5 females participated in the study; 15 were treated at Cleveland, 4 in the Bronx, and 1 at San Diego. The age at injury (yrs) was 32.2±11.1. The neurological level of injury was C5 through T12. The time from injury to implant (yrs) was 8.5±7.1. The mean length of follow-up was 21 mo. Before implantation, 14 individuals used intermittent catherization and 6 used permanent catheterization for bladder emptying. After implantation, 1 used intermittent catheterization and 19 used the neuroprosthesis for micturition. Post-voiding residual volume (ml) following micturition using the neuroprosthesis was 25.9±31.9 (median) ranging from 3.0 to 136.7 ml. The bladder capacity (ml) prior to implantation was 260±131 and increased to 467±120 following implantation. Prior to implantation, symptomatic bladder infections/year occurred at a rate of 5 (median) and ranged from 0 to 13 occurences.

After implantation, the rate was reduced to 1 (median) with a range of 0 to 10 occurrences. Changes were seen in gastrointestinal function (n=7) post implantation. Four individuals were feces continent pre-implantation, and 7 were feces continent post-implantation. Prior to implantation, defecation was achieved with suppositories (5 individuals), laxatives (3), digital stimulation (6), and manual evacuation (5). After implantation, defecation was achieved with suppositories (3 individuals), laxatives (2), digital stimulation (2), manual evacuation (5), and stimulator use (6). The duration of defecation pre-implantation was 3.0±1.6 hrs and was reduced to 0.9±0.4 hrs postimplantation at $p=0.018$. Median (range) bowel FIM scores changed from 3 (1–6) pre-implantation to 6 (1–6) post implantation at $p=0.03$.

No implant infections, erosions, or rejections have occurred. In two subjects the posterior rhizotomy performed at the time of implant was later found to be incomplete as evidenced by clinical testing. They underwent a subsequent posterior rhizotomy at the conus medullaris and now show clinical and urodynamic evidence of sacral areflexia, and are continent. They both use the stimulator routinely for micturition.

FUTURE PLANS—We seek to extend this evaluation to other Spinal Units within the VA in order to determine whether these clinical benefits can be replicated in other sites; what resources are required to initiate an implant program at other sites; which subjects among the population of veterans with spinal cord injury are most suited to this technique; and what is the relation of costs to benefits.

RECENT PUBLICATIONS FROM THIS RESEARCH

Functional neuromuscular stimulation. Chae J, Triolo RJ, Kilgore K, Creasey GH. In: DeLisa JA, Gans BM, editors. Rehabilitation medicine: principles and practice. Philadelphia: Lippincott; 1997.

Restoring bladder and bowel function to women with spinal cord injury. Creasey GH. In: Krotoski DM, Nosek MA et al. editors. Women with physical disabilities. Baltimore: Paul Brookes; 1996. p. 375–85.

[275] ELECTRICAL ACTIVATION OF THE DIAPHRAGM FOR VENTILATORY ASSIST

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PURPOSE—The purpose of this work is to develop a diaphragm-pacing system that will support the ventilatory needs of persons with compromised respiratory function. The unique aspect of our approach is the use of intramuscular (IM) electrodes implanted through a laparoscopic procedure rather than nerve cuff electrodes implanted through an open cervical or thoracic surgical procedure.

METHODOLOGY—These studies involve both humans and animals. Animals are used to determine safety and estimate efficacy. Humans are necessary to test our complete system.

PROGRESS—The method we have developed to activate the diaphragm reduces the risk of phrenic nerve damage, requires less time to implant and uses a less invasive implant procedure than conventional methods.

We have developed a vacuum attaching device and computer-controlled stimulation and data acquisition software to identify the preferred implant site. We also added on-line acquisition of a digitized frame from the laparoscopic video image of each test location. The captured images form a visual record to aid in logging the order and relative location of tested sites as a basis for choosing the next site or for predicting a region that indicates the location of the desired implant site. With this methodology, we can accurately locate the ideal placement site with 95 percent confidence level with four test locations (lasting a total of 15 min).

We have developed an implant instrument to safely and accurately place IM electrodes in the diaphragm muscle using an implant needle only 30 mm in length, as compared with the 300 mm needle used in previous IM electrode studies. The electrode insertion instrument enables the surgeon to approach the abdominal surface of the diaphragm from any angle, ensuring that the track of the implant needle is always parallel to the surface of the diaphragm and controlling the depth of the needle within the muscle. The needle is kept in tension away from the thorax, so as to keep the electrode close to the abdominal surface, permitting the surgeon to "see" the electrode the entire time. This tool has reduced the possibility of accidentally passing the implant needle from the abdominal cavity to the thoracic cavity, even in a diaphragm that is unusually thin due to disuse. This instrument has been used to successfully implant electrodes in both acute and chronic animal experiments.

We have developed a radio frequency stimulator control unit for the IRS-8 implantable stimulator. This programmable control unit serves as the interface between the computer and the stimulator. We plan to implement a fully implantable diaphragm pacing system in an animal September 1997.

Over the past 6 months, we have been unable to recruit volunteers from persons undergoing routine laparoscopic surgery at University Hospitals of Cleveland for our human diaphragm mapping study. In response to this, we will perform additional animal tests in preparation for our first human implant. We will continue to pursue the mapping study.

IMPLICATIONS—Cervical spinal cord injuries (above the C5 level) usually result in a loss of respiratory function. At present, treatment of this condition involves primarily mechanical ventilators, and less frequently, phrenic nerve stimulation with cuff electrodes. Both of these techniques have shortcomings.

The methods and technology we have developed will make diaphragm pacing less risky to the individual and less costly to the health care delivery system. The combined effects are expected to enhance the quality of life and independence of the ventilator-dependent population.

RECENT PUBLICATIONS FROM THIS RESEARCH

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The tissue response to epimysial electrodes for diaphragm pacing in dogs. Schmit BD, Mortimer JT. IEEE Trans Biomed Eng. In press.

[276] EFFECTS OF MEDICATIONS ON SPASTICITY IN SPINAL CORD INJURY: A QUANTITATIVE STUDY

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PURPOSE—In a previous study of spasticity and spinal cord injury (SCI), we identified a number of subjects in whom spasticity was not well controlled by current medications, demonstrating that the brain motor control assessment (BMCA) protocol, a multichannel surface EMG recording during a comprehensive, standardized examination, is both valid and useful. This BMCA protocol made it possible to separate out components of spasticity in a reliable and reproducible manner and hence to study the effects of various procedures on those components separately. Furthermore, we demonstrated that it is necessary to provide a comprehensive assessment of spasticity in such individuals to avoid misrepresenting the full magnitude of the clinical problem. We identified five components of particular importance: phasic reflexes, tonic reflexes, cutaneous reflexes, inappropriate coactivation in voluntary control, and "spontaneous" (triggered by identified/unidentified means) spasms.

The present project evaluates persons with problematic spasticity, using the procedures developed in the previous study. The long-term objective is to develop new methods of treating spasticity after SCI. In this study, specific features of spasticity and how they are altered by current medications are documented using an objective, neurophysiological method of assessment (BMCA). Subjects are evaluated as their antispastic medications are reduced. Aspects of spasticity analyzed are (in order of increasing estimated importance) phasic reflexes, tonic reflexes, cutaneous reflexes, inappropriate coactivation in voluntary efforts, and spontaneous (triggered) spasms.

METHODOLOGY—The key questions are: Can the results of the BMCA examination be used to identify and classify altered motor control features in persons with SCI who have spastic paresis, while reducing their medications? Can differences in behavior between patients whose spasticity is managed by various medications be discriminated? Will those differences be restricted to one aspect of spastic paresis, or will these differences be global, representing an overall excitability change? Will SCI subjects who are well-satisfied with their anti-spastic medication regime differ in response to withdrawal of those medications from those who are not satisfied?

By examining the responses to the elements of the BMCA (relaxation, reinforcement maneuvers, voluntary control, passive movements, tendon jerks, clonus elicitation, and plantar stimulation), we anticipate being able to identify different behaviors when anti-spastic medications are reduced. Emphasis is given to selection of subjects with problematic signs of upper motor neuron dysfunction and altered motor control (poor coordination, spasms, hypertonicity, hyperreflexia), and to careful examination of severity of the SCI. Following a carefully monitored washout phase, a comprehensive assessment battery is repeated to characterize the altered motor control in the subject. Data are analyzed and compared with the baseline, on-medication data and a profile of the main features of the altered motor control compiled. By comparing subjects on different medications and their response to reduction of those medications, conclusions regarding specific features of their spasticity and alteration of those features by pharmacologic intervention may be drawn.

PROGRESS—Relocation of the main data collection to the Dallas VA Medical Center has delayed progress toward the project goals. Initial efforts have focused on establishing protocols, demonstrating efficacy of new hardware through normative data collection, and collecting data in three series of studies in spastic SCI subjects.

RECENT PUBLICATIONS FROM THIS RESEARCH

Consistency of multi-channel surface EMG recordings: application in spinal cord injured subjects. Sherwood AM, Priebe MM, Graves DE. J Electrophysiol Kinesiol 1997;7:97–111.

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Clinical assessment of spasticity in spinal cord injury: a multidimensional problem. Priebe MM, Sherwood AM, Kharas NF, Markowski J. Arch Phys Med Rehabil 1996;77:713–6.

Motor control after spinal cord injury: assessment using surface EMG. Sherwood AM, McKay WB, Dimitrijevi MR. Muscle Nerve 1996;19:966–79.

[277] EFFECT OF MICROCLIMATE COOLING ON PHYSICAL FUNCTION IN MULTIPLE SCLEROSIS

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PURPOSE—Heat-sensitive multiple sclerosis patients (HSMS) are more adversely affected in certain activities than others; specifically, those activities requiring repeated effort. Typical "heat-induced" acute physiologic, motor, and self-perceived stress among HSMS include: the worsening of existing neurologic signs and symptoms, the development of new signs and symptoms, lassitude, and myriad fatigue symptoms. This study focused on active cooling-induced effects upon motor function, as measured by changes in: skeletal muscle strength and local endurance, systemic endurance, and dynamic and standing balance.

METHODOLOGY—We employed a one-group, two-treatment, repeated-measures, within-subjects design. Investigators and research subjects were blinded to the treatment conditions. Treatment conditions were randomly ordered and had two levels: low (sham) body cooling (LC) at 26.5 °C and high body cooling (HC) at 7 °C, and the order factor had two levels (second and third experiments). Treatment and order-effects and the interaction of these factors on the dependent variables were statistically tested through analysis of variance (ANOVA). A post-hoc Pearson r (product-moment correlation coefficient) was employed to measure the extent to which heat exchange was related to biologic and performance changes. Further analysis indicated differences due to treatment conditions (HC vs. LC) and differences between LC and HC due to order of testing or extraneous factors such as: accommodation to equipment, repeated testing, or behavioral differences, as well as correlations between heat exchange and the biologic and performance changes.

PROGRESS—Seventeen subjects have completed the treatment series.

There were significant before and after evaluation, by treatment condition, interactions in several measurement domains: strength (quadriceps), $F_{[1,15]}4.53$ ($F=3.07$, $p<0.05$), endurance task (leg cycling), $F_{[1,15]}8.84$ ($F=6.77$, $p<0.01$), dynamic balance task (tandem gait), $F_{[1,15]}6.71$ ($F=3.07$, $p<0.05$), single leg standing balance, $F_{[1,15]}7.48$ ($F=6.77$, $p<0.01$), and ambulation velocity, $F_{[1,15]}3.18$ ($F=3.07$, $p<0.05$). There were no pure order effects, however, an order by temperature by pre-post interaction in tandem gait, $F_{[1,15]}6.48$ ($F=3.07$, $p<0.05$) and ambulation velocity, $F_{[1,15]}5.61$ ($F=3.07$, $p<0.05$).

There were no order effects that contributed to differences in the main effects.

Heat exchange and motor performance gains are more highly correlated when HSMS are administered the HC treatment. Significant correlations between heat exchange and performance change occurred in 7 of the 9 motor tests with the HC treatment and only 1 of 9 with the LC treatment.

INDICATIONS—We conclude that acute, controlled microclimate body cooling among HSMS subjects at 7 °C for 60 min will effectively and safely decrease body temperature as measured by oral and tympanic methods; decrease systemic stress; and increase motor function. The motor function is measured by significant increases in strength of powerful ambulatory-muscles, in static (single leg standing balance test) and dynamic (tandem gait) coordination, and in local and systemic endurance capacity. This cooling produces heat loss within MS persons that is significantly correlated to motor function changes; that is, the greater the heat loss the greater the motor function gain. We believe these may be important findings for MS patients. Simultaneous symptomatic relief from fatigue and from loss of strength and coordination would benefit heat-sensitive MS persons.

[278] IMMUNE RESPONSES TO PNEUMOCOCCAL VACCINE IN SPINAL CORD INJURY

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PURPOSE—Pulmonary complications, with pneumonia being the most frequent, are a major cause of both morbidity and mortality in persons with spinal cord injury (SCI). Both bacterial and viral immunizations have been recommended to prevent these complications in those with neuromuscular disorders producing mechanical dysfunctions of the respiratory system. Although persons with SCI, particularly those with tetraplegia and high paraplegia, have been shown to be at increased risk for the development of serious pulmonary complications, including pneumonia, we are unaware of any studies documenting the efficacy of either bacterial or viral immunizations to reduce the incidence of these in this population. Our objectives are to document changes in immunologically related laboratory values of persons vaccinated at varying intervals after SCI; and to compare the incidence of pulmonary complications in those unimmunized with those vaccinated at varying times following injury.

METHODOLOGY—The original study entailed random assignment of persons with SCI into one of six groups following their entry into the University of Alabama at Birmingham (UAB) Hospital care system. Groups 1 and 2 were to receive pneumococcal vaccine or placebo at 72 hrs (±24 hrs) of injury. Groups 3 and 4 were to receive the vaccine or placebo at 17 days(±24 hrs) postinjury. Groups 5 and 6 were to receive vaccine or placebo at 4–6 mo postinjury. The groups were determined according to the time at which the patient was admitted to the UAB Hospital or Spain Rehabilitation Center. Following enrollment, four blood samples were collected: the first at the time of administration, the second 1 mo later, the third 2 mo later, and the fourth at 1 yr. Laboratory tests to be performed on each sample included: antipneumococcal antibody titers to four major representative serotypes, quantitative immunoglobulins, complete blood count with differential leukocyte count, liver profile, total serum protein and albumin. Subjects and controls were monitored during their initial hospitalization and by telephone postinjury at 3-mo intervals for the occurrence of respiratory or other systemic complications of pneumococcal disease. Appropriate microbiological and/or immunological diagnostic procedures were to be implemented whenever possible to determine whether or not such complications were indeed due to infection with Streptococcus pneumoniae.

Recent developments in the acute care of persons with SCI made it necessary to alter the study design and eliminate Groups 1 and 2, immunized immediately postinjury, because of the high dose of methylprednisolone often given within 8 hrs of injury. Steroid presence negates the immunogenicity of the pneumococcal vaccine for 2 weeks. All new subjects are enrolled in Groups 3, 4, 5, or 6.

Follow-up laboratory values and their scheduled obtainment were not altered otherwise. Emphasis is placed on the immunogenicity of pneumococcal vaccine, since measurable laboratory data are available. Only the reports from subjects themselves are available to document occurrence of pulmonary complications, and rarely were any attempts made to identify Streptococcus pneumoniae as an etiologic agent.

PROGRESS—Data collection instruments and accompanying syllabus have been completed and are in use. Subject identification, enrollment, administration of vaccine or placebo, follow-up, and collection of blood samples is complete. 95 persons have been enrolled in the study, none of whom experienced any adverse effects from the vaccination. Seven were lost to follow-up before all data were collected, and 48 refused to participate. Analyses of antibody levels have been performed.

[279] A LONGITUDINAL AND CROSS-SECTIONAL ANALYSIS OF WELL-BEING IN PERSONS WITH SPINAL CORD INJURY AND THEIR CAREGIVERS

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PURPOSE—Much of the research in spinal cord injury (SCI) has been focused on acute medical aspects of SCI, with relatively little emphasis being placed on follow-up concerns, particularly quality of life issues. Recent work has suggested that there is a strong relationship between both physical health and emotional well-being of the person with SCI and the existence of an effective social support system. There is very little information, however, on the impact of care demands on the caregiver who also most typically is the major source of social support. The purpose of this project is to investigate on a longitudinal basis, the relationship between the physical and emotional care needs of the person with SCI and the physical and emotional health of the caregiver at several intervals postinjury.

We shall examine the relationship between factors of well-being in persons with SCI and their caregivers, measured at preselected times postinjury; determine the association between physical and psychosocial characteristics of the person with SCI and feelings-of-burden variables in caregiver(s) at preselected times postinjury; determine the interrelationships between feelings of well-being of the person with SCI and his caregiver(s) in different cohorts over time; and determine the interrelationships between physical and psychosocial characteristics of the person with SCI and the feeling of burden in the caregiver over time.

METHODOLOGY—This is a longitudinal study consisting of four waves of data. A sample size of 100 SCI/caregiver pairs has been targeted. Individuals who identify themselves as most likely to be the primary caregiver are approached regarding participation in the study. The caregivers are administered four structured interviews: one in-person during the rehabilitation phase prior to discharge, and three by mail at 1 and 6 mo, and 1 yr postdischarge. The predischarge interview serves as a baseline of caregiver mental and physical health, as well as an indicator of anticipated burden of care.

PROGRESS—To date, 105 caregivers have been enrolled in the project and 63 of them have completed all 4 phases. Follow-up is scheduled to be completed by the end of August, 1997. Eighty-eight percent of the caregiving sample is female, 66 percent have a high school education or better, and 47 percent were employed outside the home at the time of injury. With regard to relationship to the person with SCI, 32 percent are spouses, 29 percent mothers, and 12 percent brothers. Of the persons with SCI, 78 percent are male and 57 percent have a high school education or greater; 52 percent have a cervical injury, while the remaining 48 percent have paraplegia.

Preliminary analysis of data reveals the caregivers are experiencing increasing negative affect secondary to caregiving over the first year postdischarge. Decreasing instrumental support is also apparent over the first year postdischarge.

FUTURE PLANS—Preliminary data analysis has begun. It will be descriptive and correlational. Longitudinal/causal analyses will not be able to be carried out until the project is completed.

[280] BACLOFEN PUMP: FUNCTIONAL AND NEUROPSYCHOLOGICAL IMPACT

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PURPOSE—The development of severe upper motor neuron spasticity is among the most common secondary medical complications for persons with spinal cord injury (SCI). This spasticity is often severe enough to affect the ability to independently perform routine activities of daily living (ADL), thereby causing many individuals to remain homebound, in acute care hospitals, or in nursing facilities. Oral baclofen (Lioresal) has proven to be a relatively effective agent for treating this problem. Unfortunately, oral dosage is limited by systemic toxicity and cognitive side effects such as drowsiness and lethargy. Moreover, because of baclofen's incomplete penetration across the blood-brain barrier, the concentration of drug at the site of action within the nervous system is typically low. As a result, 25–35 percent of persons with SCI do not receive adequate therapy.

Recent research has focused on the administration of baclofen intrathecally by means of a subcutaneously placed pump with a drug reservoir. This delivery system bypasses the blood-brain barrier and delivers baclofen directly into the cerebrospinal fluid surrounding the spinal cord. The purpose of this study is to examine the effects of intrathecal baclofen on cognition and the ability to conduct routine ADL independently. Incidence of any medical complications will also be determined. The cost-effectiveness of treating spasticity with intrathecal baclofen will also be addressed.

We seek to determine the degree to which spasticity is reduced following administration of intrathecal baclofen; to determine whether intrathecal baclofen administration significantly improves the ability of individuals to function independently in ADL, mobility transfers, and bowel and bladder care; to determine whether the level of cognitive awareness changes after administration of intrathecal baclofen; to assess the cost-effectiveness of intrathecal baclofen administration; and to document systemic side effects secondary to intrathecal baclofen administration.

METHODOLOGY—This time-series experiment will collect baseline data on 35 persons with SCI, followed by an experimental intervention (intrathecal baclofen administration), and subsequent data collection to assess any changes as a result of the intervention. Participants will receive a bolus dosage intrathecally of 50 micrograms of baclofen to determine the response to the medication and observe any adverse effects. Those not responding adequately (average drop of two points on their muscle tone and reflex scores) or having any significant adverse effects will be ineligible for further study. From those responding adequately, baseline data will be collected during a routine clinic visit. Data will include demographics, measures of injury and spasticity severity, muscle strength, functional independence, cognition and economics. Follow-up data will be collected at mo 1, 3, 6, 9, and 1 yr after pump implantation, and annually thereafter.

We expect to enroll an average of 10 persons annually. Data will be analyzed by paired comparisons within subjects pre- and postimplantation.

PROGRESS—Between 1994 and 1997, 28 new subjects received an intrathecal bolus of baclofen to determine response to the medication. Of these, 21 have undergone implantation of the pump. Data have been collected on their response to the medication, medical complications, functional independence, cognition, and economic impact up to 1 yr after implantation. For those who underwent bolus but not implantation, data regarding response to the medication and medical complications related to the bolus have been collected; 25 subjects responded sufficiently well to the bolus trial to be considered candidates for the implanted pump; 1 withdrew (moved); and 4 did not wish to proceed.

Ashworth scores were recorded before administration of the bolus and at 1, 2, 4, and 6 hrs thereafter on all subjects undergoing bolus injections of intrathecal baclofen and are also documented for each subject at every follow-up clinic appointment (at least every 3 mo).

All implanted subjects (except the one withdrawl) have been evaluated for each area prior to pump insertion and postoperatively at 1, 6, and 12 mo, and many of them have had a neuropsychological battery prior to surgery and at 3 mo postoperatively.

Data regarding costs for medical care, medications, and supplies prior to surgery have been obtained for persons undergoing pump implantation. For subjects post implantation, data have been obtained for costs since surgery.

Subject reports of side effects are documented at each follow-up clinic appointment. There has been one case of catheter failure and one pump site infection.

FUTURE PLANS—We shall continue following enrolled subjects described in protocol for data collections and implanting five to seven persons per year with pumps.

RECENT PUBLICATIONS FROM THIS RESEARCH

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Prospective study on the use of bolus intrathecal baclofen for spastic hypertonia due to acquired brain injury. Meythaler JM, DeVivo, Hadley M. Arch Phys Med Rehabil 1996;77:461–6.

[281] SARCOPENIA EARLY AFTER COMPLETE SPINAL CORD INJURY

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PURPOSE—The purpose of this study was to determine alterations of skeletal muscle during the first 6 mo after complete spinal cord injury (SCI). Cross-sectional studies of humans years after SCI suggest that complete SCI results in atrophy, conversion to more fast fibers, and less resistance to fatigue. Studies of lower mammals show that these responses are evident within 6 mo of injury. Whether humans present a comparable time frame is not known. This is important because conversion to fast muscle, with its high energy demand of contraction and limited ability to maintain force, is believed to limit the use of rehabilitation therapies.

METHODOLOGY—Subjects with complete SCI are studied 3 times; after they are clinically stable, about 6 wks after SCI (POST1); 1 mo later (POST2); and 3 mo later (POST3). On each occasion, magnetic resonance (MR) images of the thigh and calf are taken, the left m. quadriceps femoris is electrically stimulated and biopsies of the right m. quadriceps femoris are taken. Nonimpaired controls are studied at POST1 and POST3.

PROGRESS—Testing of five subjects and five controls is complete. Data from POST1 and POST3 are presented.

PRELIMINARY RESULTS—Subjects showed a 40 percent decline in fiber cross-sectional area (CSA). This was especially evident in type IIa fibers. Fiber type percent, based on histochemical analyses, showed no change. Succinate dehydrogenase and alpha-glycerolphosphate dehydrogenase activities tended to increase, especially in type I fibers. CSA for m. gastrocnemius, determined from MR images, decreased 26 percent. M. soleus and tibialis anterior showed decreases of 7 and 3 percent, respectively. Electromyostimulation (1 s 30 Hz trains of 450 μsec biphasic square wave pulses with 2 s rest between trains) for two bouts of 20 isometric actions with 2 min rest between bouts was used to assess contractile function. Subjects showed a 10 percent decline in torque for bouts 1 and 2 POST1. By POST3 torque decreased about 20 percent for each bout. They also showed greater fatigue over bouts with time, 15 percent at POST1 and 30 percent by POST3. Controls showed a 10 to 15 percent decline in torque within each bout and complete recovery between bouts at POST1 and POST3. Time to peak tension (TPT) and one-half relaxation time (1/2 R) were assessed during these tests: TPT increased about one-sixth for subjects over time and did not change during exercise; 1/2 R was also not influenced by exercise, but was longer at POST3 than POST1. SCI values at POST1 for TPT were comparable to those of able-bodied controls. Controls showed shorter 1/2 R, however, at POST1.

FUTURE PLANS—These results suggest that human skeletal muscle does not become more fast twitch, contract faster, show a decrease in aerobic enzyme content, or show preferential atrophy of slow muscle 6 mo after complete SCI. These data are at odds with general dogma. As a result, we will focus on the early responses of human skeletal muscle to SCI. More subjects are being recruited and followed the first 6 mo after SCI. If the preliminary results hold up, they will show that the major adaptive response of human skeletal muscle to extreme disuse for up to 6 mo is atrophy. This affords an excellent opportunity. Therapies for functional electrical stimulation and/or assisted standing and walking used early after injury will not need to be designed to maintain skeletal muscle fiber type composition, or attempt to convert fast fibers back to slow. Instead, they could concentrate on maintaining muscle mass.

RECENT PUBLICATIONS FROM THIS RESEARCH

Changes in physical capacity and physical strain in persons with acute spinal cord injury. Morrison SA, Melton-Rogers S, Hooker SP. Top Spinal Cord Inj Rehabil 1997;3:1–15.

C. Spinal Cord Regeneration

[282] ENHANCED CARBON FILAMENT PROSTHESES AS SUBSTRATES FOR REGROWTH OF INJURED SPINAL CORD: IMMUNOCYTOCHEMICAL STUDIES

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B742-RA)*

PURPOSE—The purpose of this study was to determine the effect of implantation of carbon filaments and fetal spinal cord tissues, both separately and together, on the growth of CGRP-positive sensory neurites and injury-associated astrogliosis, following severe spinal cord contusion injury in rats by *in situ* immunoflourescence.

METHODOLOGY—Adult rats were anesthetized and subjected to a severe contusion injury at the T8 level. The rats were divided into five groups: Group One consisted of normal controls (n=5); Group Two consisted of rats whose lesion sites were subsequently filled with a bundle of approximately 10,000 carbon filaments of 5 μm in diameter (AMOCO Thornel) cultured with 15-day-old rat fetal spinal cord explants (n=5); Group Three consisted of rats that received fetal spinal cord tissue implants after injury (n=10); Group Four consisted of rats that received carbon filament implants after injury (n=5); and Group Five consisted of rats that sustained a contusion injury only (n=5). The implantation was performed 1 to 2 hrs postinjury. Following surgery, the animals were cared for in the intensive care area of our AAALAC-certified Animal Facility. After a 10-wk survival period, all animals were perfused with 4 percent buffered (100 mM phosphate buffer, pH 7.2) paraformaldehyde. Immunofluorecence studies were performed on 12 μm-thick paraplast sections to assess immunoreactive CGRP for sensory neurites.

The astroglial response was assessed by *in situ* expression of immunoreactive glial fibrillary acidic protein (GFAP), and the neuro-axonal profile was assessed by immunoreactive phosphoneurofilament protein (NF).

RESULTS—CGRP-immunoreactivity (CGRP-IR) was found to increase at the edges of the lesion, but not within the lesion, following severe contusion injury as compared to controls. The implantation of carbon filaments, or fetal spinal cord tissue, resulted in the attritional sprouting of CGRP-positive neurites within the lesion cavity. The co-implantation of carbon filaments together with fetal spinal cord tissue further enhanced the growth of CGRP-positive neurites within the lesion cavity. The dramatic increase of GFAP-IR surrounding the cyst at the site of the lesion following contusion injury, as compared to controls, indicated injury-associated astrogliosis. The increased expression of NF-IR in terminal clubs of the injured axons surrounding the cyst at the site of the lesion showed axonal swelling due to the accumulation of NF following contusion injury, as compared to controls. The implantation of carbon filaments, and carbon filaments co-cultured with fetal spinal cord tissue limited the astroglial response as evidenced by the depletion of GFAP-IR, and by the growth of NF-IR positive axons over the carbon filaments.

We therefore conclude that the implantation of carbon filaments may facilitate neuronal regeneration by reducing astrogliosis and providing scaffolding and directionality to axons.

FUTURE PLANS—Previously we have reported electrophysiological recovery, as determined by somatosensory-evoked potentials and motor-evoked potentials, in the group of animals that received carbon filament implants cultured with fetal spinal cord tissue. In addition, retrograde labelling showed labelled axons and cells across the lesion in the group that received carbon filament implants cultured with fetal spinal cord tissue, as compared to the other three injury groups. These results of our study suggest that the transplantation of the combination of carbon filaments and fetal spinal cord tissue play an important role in promoting spinal cord functional recovery after injury. We are currently in the progress of further evaluating the use of these implants for the repair of the spinal cord after injury.

RECENT PUBLICATIONS FROM THIS RESEARCH

Carbon filaments reduce astrigliosis and provide directionality to axons following contusion injury to the spinal cord. Chauhan NB, Sayers S, Liu LS, Figlewicz H, Khan T. J Neurochem 1997;69(suppl):S150.

[283] ELECTRIC FIELDS AND CARBON FIBERS IN THE TREATMENT OF SPINAL CORD INJURY: COMPARISON OF DIFFERENT CURRENT LEVELS

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PURPOSE—Last year, we noted that various degrees of electrophysiological recovery were achieved after the application of a small 25 μA current around the lesion area in severely injured cat spinal cord. Furthermore, the animals receiving carbon filament implants, in addition to electrical stimulation of the injury site, have shown some weight bearing in addition to electrophysiological recovery. This study is designed to evaluate the functional benefit of the application of different amplitudes of pulsed DC electrical currents following severe contusion injury to the spinal cord in cats.

METHODOLOGY—Seventeen cats were anesthetized, and sustained a severe contusion injury to their spinal cord at the T8 level by dropping a 30 g weight from a height of 18 cm. A mid-dorsal myelotomy was performed 1–2 hrs after the contusion injury; by this time edema and hemorrhage develop extensively in the center of the injured spinal cord. Utilizing an operating microscope, the hemorrhagic and edematous tissue was removed by aspiration leaving a small cavity. The dura was sutured using 7-O suture.

The animals were divided into five groups. In Groups One and Two, cats received a dorsal myelotomy and subsequently received implantable stimulators 2 hrs after injury. In Group Three, cats received a dorsal myelotomy and carbon filament implants 2 hrs after injury. In Group Four, cats received a dorsal myelotomy and carbon filament implants, in addition to implantable electrical stimulators 2 hrs after injury. Group Five served as a control group in which cats underwent a dorsal myelotomy 2 hrs after injury.

In Group One, battery-powered stimulators, with 2 mm diameter platinum disc electrodes, were surgically implanted with the electrodes for current application configured to produce current flow parallel to the long tracts of the spinal cord across the injury site. The stimulation parameters were 25 μA pulsed direct current, which results in a 100 Hz unipolar square wave with a 20 percent duty cycle. In Groups Two and Four, the stimulation parameters were the same as in Group One; however, the current level was increased to 33 μA.

All animals received daily care in AAALAC certified Animal Facility. Electrophysiological and behavioral tests were performed before injury and then monthly after injury throughout the duration of the 1 yr experimental period.

RESULTS—Various degrees of electrophysiological recovery have been observed in the animals that received implantable stimulators with 25 μA current after severe contusion injury. However, the animals receiving electrical stimulation with 33 μA at the injury site have consistently shown weight-bearing and minimum ambulation, in addition to electrophysiological recovery within 6 to 8 mo after surgery and electrical stimulation. No difference in functional and electrophysiological status was observed between groups Two and Four. The control animals, and animals receiving carbon filament implants, have all remained paraplegic at the end of the experimental period.

These preliminary findings indicate that the application of an electrical field provides a favorable environment at the lesion site which results in functional recovery, and that this recovery is dependent on the current level.

FUTURE PLANS—We will continue to evaluate the different parameters of the electric fields (frequency, duty cycle, and current) in search of the ideal parameters which will bring about optimal functional recovery after severe contusion injury to the spinal cord. Recovery will be evaluated electrophysiologically, behaviorally, and histologically in order to determine the beneficial effects of electrical stimulation of the injury site as a means of repairing the damaged spinal cord.

RECENT PUBLICATIONS FROM THIS RESEARCH

Effect of applied electric fields on astrocytic scar formation after spinal cord injury. Khan T, Chauhan N, Sayers S. Proceedings of the Second World Congress for Electricity and Magnetism in Biology and Medicine; 1997, Bologna, Italy.

Functional recovery after spinal cord injury using carbon filaments and electrical stimulation. Khan T, Sayers S, Liu LS, Myklebust J. J Spin Cord Med 1996;19:271.

[284] DEVICE FOR TREATMENT OF PERIPHERAL NERVE INJURY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B687-2RA)*

PURPOSE—The purpose of this project is to develop a prosthesis that will enhance nerve regeneration in the event of a nerve transection. Previous experiments have shown that a collagen-glycosaminoglycan (CG) matrix, ensheathed in a silicone tube, promotes regeneration across a 15-mm gap in the rat sciatic nerve. The current effort is to evaluate the long-term regeneration through collagen tubes, either empty or filled with the CG matrix, based on structural and functional measurements.

METHODOLOGY—Collagen-glycosaminoglycan (CG) matrices with axial pores 5-10 μm in diameter, were prepared following an established laboratory protocol. The matrices were implanted into 10-mm gap injuries in the rat sciatic nerve within silicone or collagen tubes. Empty collagen and silicone tubes and sciatic nerve autografts were used as controls. To assess the performance of the implants, a variety of methods were employed, including light and electron microscopy, computerized image analysis, immunohistochemical staining, *in vivo* and *in vitro* electrophysiology, gait analysis, and sensory functional testing. Regeneration was assessed at 6, 30, and 60 wks.

PROGRESS—The long-term evaluation of the fully resorbable devices has been completed.

RESULTS—The CG matrix, ensheathed by silicone and collagen tubes, was shown to enhance the morphological and electrophysiological recovery of nerves regenerated across 10-mm gaps at 30 and 60 wks, compared to empty tube controls. Morphologically, analysis of variance (ANOVA) revealed that the matrix significantly increased the total number of myelinated axons per nerve, the total number of large diameter (d[Lx]6 μm) myelinated fibers and the mean fiber diameter of the regenerated nerves ($p<0.001$ for each) when compared to empty tubes. Large axons are important since axons larger than 6 μm have likely reached a distal target. By 60 wks, the regenerated nerves in all groups contained many more axons than normal, but significantly fewer large diameter fibers. The compound nerve action potentials, recorded *in vitro,* revealed significant increases in the conduction velocity and amplitude in matrix-filled tubes, compared to empty tubes ($p<0.01$ for each, ANOVA).

Several differences were apparent when comparing silicone and collagen tubes. In the collagen tubes, both empty and matrix-filled, the regenerated tissue completely filled the interior of the tubes. In contrast, the regenerated tissue filled only half the tube cross-section in the matrix-filled silicone tubes and less than 10 percent in the empty silicone tubes. The collagen tubes also resulted in regenerates which were significantly closer to normal in structure and function than nerves regenerated through the silicone tubes.

Using the total number of large myelinated fibers (d[Lx]6 μm) per nerve, a linear relationship was established between 6 and 60 wks for each prosthesis group. ANOVA indicated that the regression was significant for each implant group ($p<0.001$). The CG matrix significantly increased the slope in the silicone and collagen tubes compared to the empty tubes ($p<0.01$).

By 60 wks post-operative, the matrix-filled collagen implants had the largest number of axons per nerve (16,000±1,800), significantly more large diameter axons (2,400±200), and a significantly higher conduction velocity (50±2 m/s) than all other tube groups ($p<0.001$). More importantly, the nerves regenerated through the matrix-filled collagen devices were not significantly different from the autograft group based on all measurements at 30 and 60 wks.

IMPLICATIONS—These findings suggest that a CG matrix-filled collagen device can be used clinically as an alternative treatment to the autograft, resulting in similar morphological and electrophysiological recovery. However, the performance of the best prostheses resulted in only a 50–75 percent recovery of normal structure and function. This indicates that devices need further optimization to fully restore normal function.

RECENT PUBLICATIONS FROM THIS RESEARCH

Histological response to a fully degradable collagen device implanted in a gap in the rat sciatic nerve. Chamberlain LJ, Yannas IV, Hsu H-P, Spector M. Tissue Eng. In press.

XV. Wheelchairs and Powered Vehicles

A. General

[285] DESIGN AND SELECTION GUIDELINES FOR WHEELCHAIR RIDER COMFORT

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B805-2RA)*

PURPOSE—The goals of this research are to determine factors related to ride comfort; to record actual wheelchair road loads; and to evaluate the performance of selected wheelchairs on ANSI/RESNA standards. Ultimately, this research should improve wheelchair design and selection procedures leading to more durable and comfortable wheelchairs which are less likely to lead to disabling secondary conditions (e.g., pain and spinal-pelvic deformities).

METHODOLOGY—This is a complex study addressing wheelchair design in a comprehensive way. Surveys and accelerometry are being used to assess wheelchair rider comfort. Seven different wheelchair models from various manufacturers are being evaluated. Subjects ride the wheelchairs over a predefined obstacle course that has events similar to those encountered during normal activities of daily living. Upon completion of the course, each subject is asked to complete a survey about the obstacles and the course as a whole.

Accelerometer data is collected from the seat and bite-bar (head) in three dimensions. The data are used to develop periodograms and transfer functions. This information is being used to determine whether some wheelchairs are better at attenuating impacts and vibrations from the ground. It is also being compared to rider reported comfort.

Road load data are being collected to determine the actual loads experienced by users and their chairs, data critical for innovative design using computer-aided engineering and essential for using new materials that may lead to improved quality and lower life-cycle cost among wheelchair products. Actual road load data are being compared to that collected with the same instrumentation on ANSI/RESNA test machines. These data will be useful in improving the test methods to obtain accelerated results which are comparable to actual usage.

PROGRESS—As part of the ANSI/RESNA standards evaluation process, we have tested nearly 30 wheelchairs (depot, lightweight, and ultra-lightweight) to class III failure which would resulted in a significant degradation of performance or safety risk. Our results indicate quality striation increasing from depot to lightweight to ultralight weight wheelchairs. This is reflected in quality (i.e., number of cycles to failure) and value (cycles per dollar). Our results further indicate that similar products from different manufacturers tend to yield similar results. Strain gage data on some of the models of chairs is being used to develop S-N curves for fatigue equations to predict cycles to failure at critical points.

Ride comfort data have been collected using methods adopted from ISO 2631 and a survey on seven different wheelchairs evaluated by about 20 users. The survey addresses comfort while traversing various obstacles over a predefined course and ergonomic questions. The results indicate that there are differences between rider perceived comfort related to wheelchair model. Accelerometer data were also collected between the seat and rider's head. These data are being analyzed to determine whether variables relating seat-to-head acceleration are correlated with rider comfort.

The ANSI/RESNA fatigue tests were largely developed through consensus with little supporting data. The tests have served to improve the quality of wheelchairs. However, it is difficult to determine whether the tests are realistic and provide an accurate assessment of useful life. Moreover, data are required to apply computer-aided engineering techniques to wheelchair design. To this end, we developed instrumentation to record rear hub and front caster forces and moments. The instrumentation is portable and is being used to collect data in the laboratory, during normal use in the community, and on ISO test machines. Data have been collected with 20 subjects in the laboratory, 11 subjects during community use, and with an ISO dummy during ANSI/RESNA fatigue testing.

RESULTS—Our results indicate that ride comfort does vary among different models of wheelchairs. While there is considerable spread among some of the data, they do tend to show significant trends that appear to be stable as the number of subjects increases. Accelerometry data does appear to be correlated with self-reported rider comfort.

The road load data indicates that wheelchairs experience more frequent and higher magnitude loads on the test machines than during actual driving. This may explain why some wheelchairs tend to experience low-cycle fatigue on testing machines. Some of the loads experienced infrequently by wheelchairs during community driving are quite high. High loads are likely to be associated with curb descents. Community and test machine load data can be accurately described by statistical distributions. This should promote incorporation of the data into design processes.

FUTURE PLANS—We plan to continue increasing our sample size, to look at the influence cushion type may have on rider comfort, and the relationship between road and test loads. Currently, the focus has been on manual wheelchairs. It is important to extend this work to electric-powered wheelchairs and scooters. Very little comfort, load, or testing data are available for these devices. Our results indicate that modifications to the ANSI/RESNA fatigue tests may be appropriate to obtain results more similar to those obtained during actual use. Of course, the test procedures must take into account the accelerated time frame required of standards testing in order to be useful for design and evaluation. This line of research shows promise to benefit people who use wheelchairs, and the results have opened several areas for more intense investigation.

RECENT PUBLICATIONS FROM THIS RESEARCH

Frame failures of welded tube manual wheelchairs. Gonzalez J, Cooper RA, Rentschler A, Lawrence B. Proceedings 20th Annual RESNA Conference; 1997, Pittsburgh, PA. Washington, DC: RESNA Press; 1997. p. 184–6,

An improved method for measuring power wheelchair velocity and acceleration using a trailing wheel. Lawrence B, Cooper RA, VanSickle DP, Gonzalez J. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press; 1997. p. 251–3.

SMARTACCELEROMETER: a device to measure three-axis acceleration for the purpose of evaluating wheelchair rider comfort. VanSickle DP, Cooper RA, Gonzalez J. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press; 1997. p. 245–7.

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Wheelchairs and seating. Brienza DM, Cooper RA, Brubaker CE. Curr Opin Orthop 1996;7:82–6.

[286] ERGONOMICS OF MANUAL WHEELCHAIR PROPULSION

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PURPOSE—Systematic analysis of manual wheelchair propulsion from a combined biomechanical and physiogical perspective may eventually improve the mobility of the wheelchair-user combination. We study the impact of wheelchair design characteristics upon the physiology and biomechanics of the wheelchair user, with special reference to functional load and mechanical efficiency and kinetics, loading of structures during mere manual wheelchair propulsion. From this, a set of theoretically based guidelines for wheelchair design and wheelchair fitting emerges. We also study the factors that determine work capacity and power output (among others: functionality and propulsion technique) of the wheelchair user. This should lead to guidelines of wheelchair training in sports and rehabilitation, and additionaly serve in the development of design and fitting guidelines of wheelchairs.

METHODOLOGY—Wheelchair propulsion is studied during standardized submaximal aerobic wheelchair exercise and sprint tests on a motor-driven treadmill and during simulated conditions on different computer-controlled wheelchair ergometers. During the treadmill tests (used in studies on prototype evaluation, performance capacity, and propulsion technique), physiological measures are combined with 3-D kinematics and electromyography. Force measurements and kinematics during propulsion on the wheelchair ergometer enable an additional 3-D reconstruction of the movement pattern of arms and trunk and the study of force and power production. Together with electromyography of shoulder, arm, and trunk muscles and overall physiology, phenomena of the low and varying mechanical efficiency in manual wheelchair propulsion may be studied from a biomechanical and anatomical perspective.

A detailed model of the shoulder-arm complex allows calculation of the contribution of different muscles on power production during static and dynamic activity of shoulder and elbow in wheelchair arm work and other tasks. Thus the high prevalence of repetitive strain injuries (RSI) in the shoulder and hand-wrist area among the wheelchair-user population may be understood more clearly. Currently, a system is implemented that allows the ambulant measurement of 3-D wrist excursions during wheelchair propulsion. Arm work during different forms of manual wheelchair propulsion is thus studied: lever, crank, hubcrank, and hand rim propulsion.

PROGRESS—Detailed studies were conducted on lever and (synchronic and asynchronic) crank propulsion in relation to different gear ratios. Results indicated a significantly better performance using the synchronic mode. The levers showed a better performance when using a ''high resistance/low speed'' condition. Overall, levers and cranks are much less straining and more efficient than handrims. The latter also holds for hubcrank propulsion. A first study of hand-wrist motions indicated large excursions around the flexion/extension axis and ulnar/radial deviation axis.

FUTURE PLANS—We shall work on further refinement of fitting quidelines for groups of impaired subjects, also during the process of rehabilitation. Detailed analysis of wheelchair arm work during hubcrank and handrim propulsion must contribute to a further understanding of the mechanisms and risks of RSI and possible preventive measures in terms of wheelchair design or propulsion technique.

RECENT PUBLICATIONS FROM THIS RESEARCH

Mechanical advantage in lever wheelchair propulsion: effect on physical strain and efficiency. Woude LHV van der, Botden E, Vriend I, Veeger HEJ. J Rehabil Res Dev 1997;34(3)286–94.

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Physical strain and mechanical efficiency in hubcrank and handrim wheelchair propulsion. Woude LHV van der, Kranen E van, Ariens G, Rozendal RH, Veeger HEJ. J Med Eng Tech 1995;19(4):123–31.

[287] THE DETERMINATION OF ENVIRONMENTAL ACCESSIBILITY AND WHEELCHAIR USER PROFICIENCY THROUGH VIRTUAL SIMULATION

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PURPOSE—In an effort to utilize technology that can have a direct and immediate relevance to the problems confronting persons with disabilities, we propose to examine human performance in negotiating barrier-free environments through the use of computer-generated virtual simulations. The project will be instrumental in defining standards for use in evaluating user proficiency, which will provide information for more suitable selection of assistive technology (AT). In addition, this research will demonstrate direct implications to the development of AT through virtual testing and analysis, and provide improved methods for designing barrier-free environments.

METHODOLOGY—We will interface Invacare's Action Power Evaluation and Training simulator with a computer simulations. We will incorporate "real world" architectural databases, so as to maximize transfer from the simulator to actual user environments. We propose that this research will demonstrate feasibility toward a practical interface for for use in analyzing and evaluating human performance, and provide us with new insight into the nature of disabilities and new understanding of certain limitations.

PROGRESS—We have developed a system that integrates computer visualization with innovative interface technology to create a virtual environment that simulates the movement of a power wheelchair through synthesized architectural environments. For architects and designers, this system provides structure, previsualization, and analysis that can both improve the accessibility of building designs and test a structure for compliance with the ADA; for wheelchair users, it provides more appropriate device fitting and training with control systems; and for health care professionals, it provides a way to assess user performance and for determining the best power chair control mechanism for a particular user.

The system consists of an instrumented, joystick-driven power wheelchair connected to a high-performance graphics workstation. The user, wearing 3-D glasses, sits in a wheelchair utilizing a standard joystick interface to navigate through a computer-synthesized environment. The system depicts the dynamics of the wheelchair in the particular environment. The virtual chair moves with the same speed and turning radius as a chair in the physical world.

Two primary modes of operation were supported for the joystick: passive and active. In passive mode, the joystick will discourage the driver from going toward obstacles by making it harder to push the joystick in those directions. Active mode allows the joystick to exert a force that will guide the user toward a less congested area.

We are integrating a head-mounted display with the system to provide the precise location of objects in the user's field of view at the time of reaction. All of this information is automatically filed for the evaluator, providing a comprehensive analysis of the user's performance.

Pilot trials have been run at the Ohio Supercomputer Center with individuals with disabilities of varying severity and controls. Simple steering tasks were performed and evaluated as the subjects navigated a simple environment using a joystick controller.

RESULTS—To date, we have developed a robust system that provides previsualization of architectural data sets and assists in assessment for ADA compliance. In addition, the system provides an immersive environment for users to train themselves in the use of a powerchair, thereby limiting the application of unsuitable technology that may never be fully, or even partially, utilized. Also, we are completing an evaluator's environment for trials to evaluate individuals in power chair proficiency.

RECENT PUBLICATIONS FROM THIS RESEARCH

Assessing user proficiency through virtual simulations. Stredney D, Yagel R, Carlson W, et al. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press, 1997. p. 366–8.

[288] BRAKING STUDY

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Sponsor: *Paralyzed Veterans of America, Washington, DC 20006; Eastern Paralyzed Veterans of America*

PURPOSE—Many power wheelchair users have paraplegia, quadriplegia, or cerebral palsy. Because of their conditions, they lack sufficient muscle strength or control to hold the body in an upright seated position, especially when subjected to forces associated with braking. There are about 36,000 serious wheelchair-related accidents annually, the majority of which are attributed to falls and tips. Our goal is to reduce this number by investigating the reason why these falls occur. Our hypothesis is that safety and support devices such as seatbelts and footrests are not always used by the wheelchair occupants, compounding problems. We will correlate the risks of injury due to falls with the use of said devices.

METHODOLOGY—A fiftieth percentile anthropometric crash test dummy (ATD) was used to simulate a human occupant of a power wheelchair. The dummy was seated in a power wheelchair and the chair accelerated to its maximum velocity. When the chair reached a line on the floor, a braking condition was enacted. The response of the dummy and the chair was recorded via a digital video camera. Reflective markers were placed on 9 anatomical positions of the dummy and 6 locations on the chair so that the camera could capture the position versus time of the wheelchair and body segments of the ATD. The recorded images on video are digitized and analyzed using a Peak5 Motion Analysis System.

The test protocol includes three braking conditions: kill switch activation, joystick release, and full reverse of the joystick. Four adjustments were made to each wheelchair: seatbelt and footrests on, seatbelt on and footrests removed, without the seatbelt and footrests attached, and with neither seatbelt nor footrests in use. This gives a total of twelve combinations tested on each chair. For statistical reasons, each condition was repeated three times.

PROGRESS—Eight power wheelchairs have been tested, filmed, and digitized. The data output from the motion analysis system was processed through a program written in Matlab to calculate the different kinematic parameters of the chair and dummy body segments. We are beginning statistical analysis to correlate the risk of falls and injury to the kinematic data.

PRELIMINARY RESULTS—The set-up of the wheelchair and the braking condition appear to influence driver safety. A pilot test study with two wheelchairs involving only a few wheelchair and ATD kinematic parameters showed that wheelchair condition had no significant effect on the dummy kinematics for the joystick release braking condition. However, kill switch braking conditions, in which deceleration rates are higher, showed significant differences in the kinematic data between trials in which the ATD fell from the chair and trials where it did not.

FUTURE PLANS—In the future, we would like to conduct a more comprehensive study with an increased sample size. We intend to use a HybridIII test dummy, equipped with accelerometers and force sensing gages, to acquire force data during the trials. From this kinetic data, we can acquire information as to whether bones will be broken during falls or whether restraining devices could put users at risk to injuries.

Until now, all tests have been done on a clean, dry, level, linoleum floor. This does not encompass all driving conditions the user may encounter. We would like to test on different surfaces (carpet, concrete) and on different obstacles (ramps, curbs).

Part of the problem is lack of awareness. Power wheelchair users need to be notified so that they understand that they are accepting a potential risk by removing footrests and not wearing seatbelts.

We would like our research to result in the establishment of safety standards associated with characteristics of the power wheelchair, such as maximum deceleration and braking distance.

RECENT PUBLICATIONS FROM THIS RESEARCH

Kinematic analysis of anthropometric test dummy during power wheelchair braking. Dvorznak MJ, Cooper RA, O'Connor TJ, Boninger ML. Proceedings of the 20th Annual RESNA Conference; 1997 Jun 20-24, Pittsburgh, PA. Washington, DC: RESNA Press; 1997. p. 257–9.

B. Powered Controllers

[289] DESIGN OF A MOTORIZED PRONE CART

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B1522-3DA)*

PURPOSE —The goal of this project is to develop a new motorized prone cart, the last phase in the design of new prone carts by this team of investigators.

Prone carts are used by individuals with spinal cord injuries (SCI) who have pressure sores on the sacral region and the legs. Once pressure ulcers develop, the patient must stay off affected areas until they are healed. In most instances, this precludes the use of a wheelchair. Prone carts provide an alternative to prolonged bed immobilization for persons with ischial or sacral pressure ulcers who must lay on the side or in prone position.

Motorized prone carts are used by individuals with SCI who have limited, or no, arm and hand functions (quadriplegics), while manual prone carts are used mostly by individuals with arms and hand functions (paraplegics).

METHODOLOGY—This project will be accomplished in three phases. First, we shall design and fabricate two motorized prone carts with Ortho-Kinetics, the collaborating manufacturer. Each will be equipped with a different controller system. Then we shall evaluate the carts with patients at the Milwaukee and Tampa SCI Centers as well as in wheelchair accessible homes. This evaluation will include a combination of questionnaires, interviews, and photography to validate the prototypes. Finally, we shall Test the new carts with applicable ANSI/RESNA Electric Wheelchair Standards: determination of dynamic stability (WC/02); determination of efficiency of brakes (WC/03); determination energy consumption (WC/04); determination of overall dimensions, mass, and turning space (WC/05); determination of maximum speed, acceleration, and retardation (WC/06); static, impact, and fatigue strength tests (WC/07); climatic test (WC/09); determination of the obstacle climbing ability (WC/10); testing of power and control systems (WC/14); and determination of flammability.

PROGRESS—The design and fabrication of two prone cart frames has been accomplished. The investigators await power base and controller units, in order to mount them on the frames prior to beginning clinical evaluation.

FUTURE PLANS—Based upon the evaluation, the prototypes will be modified if necessary, before completion of the project and testing with applicable ANSI/RESNA Electric Wheelchair Standards.

C. Seating Systems

[290] SEATED AND RELATED POSTURAL DEVICES FOR ELEMENTARY SCHOOL ENVIRONMENTS

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PURPOSE—The purpose of this project is to develop school furniture that has universally accessible design features. We plan to identify consumer needs and the issues related to posture and school work to design and develop new furniture for use by most students with or without physical disabilities.

METHODOLOGY—Qualitative methodologies were applied to acquire new information about the product needs of elementary school students. Initially, unstructured interviews were conducted with 15 key informants: teachers, teacher assistants, principals, occupational and physical therapists working in schools, and educational consultants. Next, we developed and administered a self-report questionnaire using the relevant variables identified by the key informants and issues discussed in the literature.

PROGRESS—Sixty-four responses were received from a sample of 123 questionnaires (52 percent return). Respondents expressed a pressing need for chairs and desks that fit children better. However, capital funding constraints in schools will clearly curb the commercial success of our products if we compete against simple, low cost school furniture. The results are now being used to establish criteria for various designs. We plan to work with consumers to evaluate these novel design solutions.

[291] AN IMPROVED ANTERIOR PELVIC STABILIZER

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Sponsor: *The Ontario Rehabilitation Technology Consortium funded by the Ontario Ministry of Health*

PURPOSE—In our effort to understand the concerns of consumers who use seating products, we have discovered that postural belts appear to be the source of greatest dissatisfaction. To address this, a project was begun to focus our developments on these components.

METHODOLOGY—We will work at improving the functional design of the anterior postural control systems with the help of consumers and service clinicians. Survey, focus group techniques, and family trials will be used to evaluate current belting approaches to support the development and commercialization of new, innovative alternate designs.

PROGRESS—Since 1994, development has progressed to a state where pre-production prototypes of two products have been or currently are being clinically tested. Based on needs expressed by consumers and clinicians, two directions were pursued: the Hip Huggers were developed to increase the efficacy of regular lap belts, while the Rigid Pelvic Stabilizer System was designed to replace postural belts entirely, particularly for children with complex seating problems.

FUTURE PLANS—The design phase for both devices is virtually complete. The clinical trials will be completed, and the devices will be turned over entirely to their respective industrial partners.

[292] CUSTOM CAR SEATS FOR SCHOOL-AGED CHILDREN WITH PHYSICAL DISABILITIES

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PURPOSE—Many children with physical disabilities need custom-made seats to be comfortable and well-supported while in their wheelchairs. This creates safety concerns for parents wanting to transport their child in the family car. Commercially available car seats are often not suitable because many of these children do not fit into them. As a result, parents use the custom-made seat from their child's wheelchair for this purpose. This arrangement may not provide adequate protection for the child in case of collision.

METHODOLOGY—We are working to develop a custom car seat for school-aged children weighing from 40 to 75 pounds. In this way, they will be comfortable, yet be offered the same level of occupant protection as other passengers in motor vehicles. Parents are also concerned about how to transfer their child safely to and from the car without injuring their backs. To help them deal with this problem, we also developed a portable lift and transfer device for this purpose.

PROGRESS—To reduce manufacturing costs and improve the designs, efforts focused on repackaging both the child restraint system and lifting device. The power source of the lifting device was changed from a rechargeable unit to the car battery to increase its reliability and battery life.

FUTURE WORK—We will develop marketing strategies to interest companies. As part of this initiative, we will seek patent protection to guard the commercial value of our products.

[293] CLINICAL ASSESSMENT OF SEATED STABILITY DURING TRANSPORTATION

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PURPOSE—Information is needed to assess the application of simple, clinical evaluations in a static environment of the stability of individuals seated in wheelchairs during automobile driving. Reliable clinical evaluations are needed for the design of postural support belts and contoured seating systems necessary to compensate for the loss of muscular control and strength used to maintain upper body stability.

METHODOLOGY—In normal body mechanics, the stability of the torso is achieved when the trunk musculature exerts a resisting torque to balance the moment created by external forces (gravitational and inertial). The maximum torque that an individual needs to apply to maintain balance can be estimated by the test subject leaning as far as possible without falling. The horizontal displacement of the torso center of gravity (cg) at this position is defined as the stability limit. During dynamic vehicle maneuvers, the inertial acceleration generates a force to act perpendicular to the gravitational vector at the cg. The maximum tolerable inertial acceleration without loss of balance can be estimated from the stability limit and the height of the torso cg.

PROGRESS—Testing was performed with four subjects with paraplegia (T2–3 to T9) and four with quadriplegia (C5–6 to C7). The height of the torso cg of each subject was found by measuring the displacement of the cg at two tilt angles while the subject was well supported upright in the wheelchair. The forward and lateral stability limit was measured and the magnitude of the inertial acceleration to cause instability was predicted.

To compare the predicted stability to the actual, the dynamic stability of each subject was also measured using a computer-controlled tilt-table, The pitch and roll of the table simulated conservative (0.2 g) and aggressive (0.4 g) driving maneuvers, reproducing previous on-road tests. The subjects were seated in a conventional manual wheelchair with a foam cushion on a platform seat with a vinyl sling back. A floor-mounted lap belt was used for safety. The wheelchair was rigidly mounted to four load cells to record the cg data throughout the test. Each subject was asked to maintain upright posture, look straight ahead, and keep his/her arms crossed to assure no assistance for stability. Release of arms from this posture was an indication of lost stability.

PRELIMINARY RESULTS—The stability limits for the subjects with paraplegia ranged from 2.39 to 7.32 cm. laterally, and 2.59 to 14.10 cm forward. From this data the predicted dynamic stability was calculated to be greater than 0.2 g for three subjects during turning maneuvers and for two subjects during braking. In each of these cases, the subjects maintained stability during conservative driving maneuvers. In each of the other driving conditions, stability was not maintained. The stability was predicted correctly in each of the eight test conditions.

For subjects with quadriplegia, the lateral stability limits varied from 3.66 to 4.78 cm, and the forward stability limits ranged from 2.36 to 5.44 cm. These measurements predicted the loss of stability below 0.2 g. Two of these individuals, however, were able to resist inertial forces during the 0.2 g turns.

The statically measured stability limit was found to be a more accurate predictor of dynamic stability than was the level of disability. This was particularly evident with one of the subjects who is a low level paraplegic, but had the smallest stability limit and was unable to maintain stability during any of the simulated maneuvers. Another subject with a static forward stability limit more than twice of any other subject was the only one who could maintain stability during aggressive braking.

FUTURE PLANS—These results indicated accurate static evaluations of the level of stability experienced while traveling in a wheelchair. Further simplification of the evaluation process will be sought to eliminate the need for complex equipment such as the tilt table and load cells. The promising concepts of the maintained maximum angular torso displacement, and the trunk muscle generated horizontal force at chest level will be investigated.

[294] STRESSES IN THE SOFT TISSUE OF THE HUMAN BUTTOCKS IN THE SITTING POSITION

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PURPOSE—Computer modeling can be used as a design tool for various types of assistive technology, including wheelchair seating systems. The long-term goal of this project is to improve the model of the material properties used in seating design. A finite element (FE) model will be generated using data collected for both soft biological tissues and cushioning materials. The ultimate goal is to develop a computer-aided design tool for creating seating systems that will reduce the risk of decubitus ulcers.

METHODOLOGY—In the initial phase of the work, a hemispherical axi-symmetric model of a portion of a single buttock was developed. For initial model development, linear elastic material properties were used with an elastic modulus of 15 kPa and Poisson's ratio of 0.49.

The model includes the soft tissues under and around the ischial tuberosity, with a rigid core representing the bony prominence, of a typical adult weighing 779 N with a hip breadth of 400 mm. It consists of a vertical cylinder, radius 25 mm, length 50 mm, with a hemispherical end (radius 100 mm). The outer hemisphere represents soft tissue and consists of 75 elements. The cylindrical core does not consist of any elements at all: rather, it is created by the use of displacement constraints placed along its interface with the soft tissue.

PROGRESS—For the purpose of initial development, several load cases were applied to the model, including hydrostatic loads over the outer surface of soft tissue, hydrostatic loads over the lower portion of the outer surface of soft tissue, and concentrated forces. The first load case approximated the external pressure created if the buttocks were submerged in 61 m of water. The second load case approximated sitting on a flat, rigid surface. These load cases were selected to facilitate comparison with published results in the literature.

PRELIMINARY RESULTS—The first load case resulted in the lowest stresses and deformation. The second load case created high stresses at the base of the rigid core, representing the ischial tuberosity. The concentrated force load case led to the highest local stresses and deformation, but the rest of the model remained in a low stress state.

Results of these load cases compared favorably with the work of previous investigators. Thus, the initial model has been verified.

FUTURE PLANS—The next step in this project is to modify the FE formulation to include nonlinear characteristics in the soft tissue. This will be followed by either modifications to the loading schemes to simulate a more realistic seat interface or the actual inclusion of FEs to represent the seating surface.

XVI. Wound and Fracture Healing

A. Pressure Sores

[295] COMPARISON OF SEMI-SYNTHETIC AND AUTOLOGOUS CONNECTIVE TISSUE GRAFTS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Pilot Project #B1839-PA); Plastic Surgery Education Foundation, Arlington Heights, IL 60005)*

PURPOSE—Chronic pressure sores are now treated by reconstructive surgery, using a musculocutaneous flap. If this fails and the ulcer recurs, as is frequently the case when causative compression of soft tissue against a bony prominence cannot be avoided, there may be no remaining donor site for a flap or graft.

METHODOLOGY—A tissue-engineered graft for repair of the deep or recurring ulcer is constructed of natural and synthetic biomaterials seeded with autologous connective tissue and fat cells, nourished either from an external fluid loop through artificial capillaries, or by a microsurgically relocated arteriovenous loop. The synthetic capillary network is a branching mesh of permeable tubes, connected either to vessels at a distance from the injury, or to a supply of culture medium. The latter takes the place of the blood supply until replaced by it; it also provides a means for infusing antibiotics to combat infection. The matrix that best mimics mechanical and geometric properties of intact tissue is an interdigitated composite of collagen and hyaluronic acid (HyA), with the collagen cross-linked using ultraviolet light to avoid toxic chemicals.

PROGRESS—A 1-yr pilot project demonstrated cell compatibility of collagen/hyaluronic acid grafts *in vitro*. These composite materials were tested for creep compliance and tensile relaxation properties. A sub-project now underway involves testing capability of these grafts to resist bacterial and fungal infections common in pressure sores. A second pilot project to perform microsurgical revascularization of semi-artificial grafts in rats includes an effort to develop a better small animal model for pressure sores.

Three physical forms of semi-synthetic graft have been created: homogeneous dispersions of random-geometry HyA particles less than 100 μm in diameter; continuous-strand HyA mats or felts; and loosely packed HyA beads 0.5–1.0 mm in diameter. These are processed into porous discs 35–60 mm in diameter and 2–5 mm thick. Methods for controlling swelling and solubility of the HyA component have been adapted from the literature. Samples of a modified Type I collagen have been provided by Nova-Gen Inc. (Fremont, CA) in addition to purchased bovine collagen and in-house prepared rat-tail collagen.

Preliminary implantations in rats were completed, using a subcutaneous abdominal site. Inflammation was minimal, with rapid capillary outgrowth from the arteriovenous loop within 2 wk and preservation of the HyA component for 8 wk. As predicted from *in vitro* experiments, migrating cells enveloped individual HyA beads or strands, and did not form a fibrous capsule around the entire implant. The abdominal site did not provide a wound margin suitable for testing integration. Alternate sites that would better emulate the clinical pressure sore include latissimus dorsi and rectus abdominus muscle excision wounds, with the latter requiring less extensive mobilization of the saphenous vein to create the arteriovenous loop.

FUTURE PLANS—A larger scale animal implantation experiment will show that restoration of tissue volume and vascular supply can be reliably replicated; this will be followed by a proposal for a limited clinical trial. Because the costs and level of surgical skill are anticipated to be lower than reconstructive microsurgery, we expect this type of graft to occupy a place in the therapeutic armamentarium midway between surgery and conservative debridement followed by semiocclusive dressings.

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[296] PREVENTION OF RECURRENT PRESSURE ULCERS AFTER MYOCUTANEOUS FLAP

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PURPOSE—The purpose of this study is to evaluate the efficacy of individualized educational interventions with structured long-term follow-up for the prevention or early detection and treatment of recurrent pressure ulcers after surgical management in persons with spinal cord injury (SCI). Included are frequent assessments of the skin care treatment program, pressure ulcer knowledge retained and behaviors practiced, assessment of equipment, assessment of psychosocial status, and the monitoring of urinary collagen metabolites. As physiologic and/or psychosocial risk factors for recurrence of pressure ulcers are identified, the information will be used to individualize the educational program and the assessment and treatment plan to prevent recurrence of surgically managed pressure ulcers in the SCI population. The primary goal of this study is to decrease the recurrence of pressure ulcers in persons with SCI after surgical management. Long-term goals include decreasing the number of hospitalizations, lengths of hospital stay, and medical costs as well as increasing quality of life for these individuals after surgical management of pressure ulcers.

METHODOLOGY—Enhanced instruction of clients and professional multidisciplinary follow-up are the independent variables of this study. Based on the Agency for Health Care Policy and Research (AHCPR) pressure ulcer guidelines, our educational program incorporated the following components: prevention, assessment of tissue damage, and monitoring of outcomes in covering the etiology and risk factors for development of pressure ulcers; the principles of wound healing and nutritional support; an individualized program of skin care; and the selection of support surfaces and equipment. Furthermore, there is a mechanism for accurate documentation and monitoring of education and treatment interventions. Subjects are randomized into one of three groups. The educational intervention is applied to subjects in Group 1. In addition to follow-up by physicians and routinely scheduled Spinal Cord Injury Outpatient Clinic visits, persons in Group 1 receive monthly telephone calls from either an occupational therapist or nurse to assess skin condition, pressure ulcer prevention behaviors practiced, and psychosocial status. Individualized education, equipment, and psychosocial needs are also addressed. Group

2 receives routine pressure ulcer education, no monthly phone contact with either the occupational therapist or registered nurse, and sends a monthly urine sample. Group 3 receives routine pressure ulcer education, no monthly contact, and no monthly urine samples. Subjects in both Groups 1 and 2 send monthly urine samples throughout the duration of the study for the purpose of determining collagen metabolite markers that may be predictive of skin breakdown occurrence. Collagen is the principal protein of the skin matrix, and it is responsible for the great tensile strength of the skin.

PROGRESS—This is the first year of this study. Preliminary results demonstrate no recurrence of pressure ulcers in those in Groups 1 or 3. Group 2 subjects have had a 40 percent recurrence pressure ulcer rate.

FUTURE PLANS—In addition to studying recurrence of surgically managed pressure ulcers in the SCI population, three additional groups will be studied: persons receiving split thickness skin grafts to surgically manage pressure ulcers, those whose pressure ulcers are debrided without surgical closure, and those with SCI whose ulcers are conservatively managed.

[297] USE OF TRETINOIN TO PREVENT PRESSURE ULCERS IN SPINAL CORD INJURY PATIENTS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #B688-2RA)*

PURPOSE—We seek to determine, through amino acid assays and collagen typing determinations on biopsies taken before and after treatment, whether skin collagen structure has been sufficiently improved to expect that the risk of developing pressure ulcers has been diminished in the treated area.

We also want to determine whether the efficacy of the treatment depends on time since injury or age of the subject by using statistical regression analysis on the data from the amino acid and collagen typing determinations.

METHODOLOGY—This is a controlled, prospective, randomized study. The protocol has been approved by the Institutional Review Board for Human Subjects.

After obtaining informed consent, a 4 mm punch biopsy will be obtained from the sacral area. The biopsy will be assayed for content of the four amino acids characteristic of collagen (hydroxyproline, proline, hydroxylysine, and lysine), and the ratio of collagen Type I to collagen Type III will be determined. The amino acids will be assayed by HPLC chromatography using methods developed by Dr Rodriguez and H. Garza. The collagen typing will be done using gel electrophoresis.

The subject population will be recruited from the VA Medical Center in Houston or attending the Spinal Cord Injury Clinic and consist of 40 male, traumatic spinal cord injury (SCI) subjects between 20 and 55 years of age who have had at least one pressure ulcer previously. Additional inclusion criteria: physiologically complete, nonprogressive SCI and normal liver function. Exclusion criteria: any metabolic disease affecting protein metabolism, presence of other neurological disorder besides SCI, or cauda equina injuries.

Twenty of the subjects will be provided with the tretinoin cream and will be shown how to apply to the skin area at risk. They will apply the cream daily for 1 year. The other 20 subjects will be given a placebo cream. The subjects and the investigators will be blinded to the treatment. The main outcome measure is an improved skin collagen biosynthesis as determined by increased amino acid content and increased content of collagen Type I.

PROGRESS—All preliminary work setting up the assay methods has been completed. Needed supplies have been obtained and questionnaires developed. Ten subjects have been recruited. We do not have any results yet. We will do the assays in batches for increased efficiency.

SIGNIFICANCE—If this study demonstrates that our hypothesis (applying tretinoin cream to the skin will improve collagen biosynthesis) is correct, it will significantly impact on the cost of treating SCI subjects by reducing the number of hospitalizations. Pressure ulcers are a very costly sequelae of SCI. Reducing the incidence of pressure ulcers in the SCI population will also improve the quality of life of the subjects and might make it possible for more of them to be active participants in community life.

[298] THE USE OF GROWTH FACTORS IN PRESSURE ULCER HEALING: CLINICAL TRIALS

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PURPOSE—Optimizing active treatment protocols for pressure ulcers requires speeding up the rate of regenerative healing in order to reduce both the likelihood and impact of other secondary complications. This project was designed to examine the use of fibrin matrices that serve as a drug delivery system for an angiogenic factor (FGF-1) as well as a regenerative scaffold. In the past we have worked on the development of biodegradable fibrin matrix for delivery of FGF-1 and on the development of a porous fibrin matrix; now we are working to evaluate clinically the pressure ulcer healing efficacy of the fibrin matrix with FGF-1.

METHODOLOGY—Clinical trials will be conducted with two treatment groups of 10 patients each. Group 1 will receive the standard clinical treatment of saline-soaked dressings and Group 2 will receive a biodegradable fibrin matrix with FGF-1 applied to the surface of the wound.

PROGRESS—It was found that the fibrin and the FGF-1 act synergistically to enhance the healing response. The FGF-1 apparently needs a matrix for the cells and blood vessels to grow into, and the fibrin matrix does not stimulate the angiogenic and healing response as well without FGF-1 incorporation.

For the porous system, which was made by adding polyethylene glycol (PEG) beads (100–200 μm) into the fibrinogen during the formation of the fibrin matrix, further optimization is needed prior to clinical testing. The current system did not give a better response in open wounds, and, in a related study with meshed skin grafts, the porous system was less effective than the nonporous, both due to its lower adhesive strength and the residence time of the PEG.

In preparation for clinical studies, effort has concentrated on development of the clinical protocol, development of clinical assessment tools, obtaining IRB approval, and obtaining FDA approval. For the assessment techniques, three aspects of pressure ulcer healing will be assessed: healing rate, tissue health, and overall clinical impression. For healing rate, the epithelialization rate, contraction rate, and tissue fill rate independent of wound size will be assessed. For tissue health, a scanning laser doppler will be used to assess the blood flow of the entire wound.

IRB approval has been obtained for two studies: 1) Assessment of control patients who receive the standard pressure ulcer clinic protocols and 2) Evaluation of a pressure ulcer patient with or without fibrin. The clinical study is currently waiting on an IND for FGF-1. Based on requirements outlined by the FDA, the protocol has been modified and the project is on hold until certain GMP requirements are met.

FUTURE PLANS—Over the next few months the emphasis will be on satisfying the FDA requirements, modifying the clinical protocol, and resubmitting to the IRB. One aspect of the FDA's ruling is that the double blind part of the study was lost. If the control group can be made to appear like the treatment, a double blind study is still possible. This however will require drawing plasma from control patients, which will not be used, applying an innocuous substance that looks like the fibrin/FGF, and requiring the control patients to have the same extra clinic visits. Additionally, efforts will continue to further optimize the porous fibrin matrix.

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[299] CHARACTERISTICS OF GENITAL SKIN FLORA IN PERSONS WITH SCI AND THEIR EFFECT ON DEVELOPMENT OF URINARY TRACT INFECTION

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PURPOSE—The nature of changes occurring in microbial ecology of the skin and urinary tract after SCI that result in establishment of diverse, antibiotic-resistant flora are complex and poorly defined. Increased understanding of these changes may lead to ways of preventing or eliminating skin colonization by urinary pathogens following SCI, and ultimately to reduced occurrence of complications resulting from UTI.

This study will determine whether there is a significant difference in skin colonization by urinary pathogens in those persons with SCI who retain normal bacterial flora of the genital skin long after injury in comparison to those who have chronic or recurrent bacteriuria. Whether the nature and degree of surface colonization and development of bacteriuria are affected by bladder management method will also be assessed.

The study will also evaluate the natural history of skin colonization in hospitalized persons with SCI, and determine whether and how administration of systemic antibiotics affects skin colonization and development of bacteriuria, by determining the relationships among urethral and perineal bacterial flora, bladder management method and bacteriuria in males with long-standing SCI, as well as the effect of systemic antibiotics on bacterial flora of the urethra and perineum in men with SCI currently hospitalized and undergoing treatment for UTI.

This study differs from prior investigations in that it includes persons injured many years ago, evaluates larger numbers of persons using different bladder management methods, and includes quantitative microbiologic procedures sufficient to detect all pertinent bacterial species and determine antibiotic susceptibility patterns.

METHODOLOGY—A cross-sectional study will examine cultures of the perineum and urethra obtained simultaneously with urine cultures and urinalysis on eligible persons who return to the UAB-SCICS clinic for routine annual evaluation. If antibiotics are being taken for any reason, these data are recorded. Also recorded are any positive urine cultures greater than 100,000 colonies/ml since their last annual and for which antibiotics were given. Persons whose urine culture is negative will be cultured again at their next annual evaluation to determine whether the characteristics of skin flora and freedom from bacteriuria persist. Only men are being included in this investigation because of the nature of the study.

The data analysis will compare the percentage of persons with each degree of bacteriuria by the method of bladder management. Next the percentage of persons with each type of bladder management who have abnormal skin flora will be compared. The results of the urethral, perineal, and urine cultures will then be used to determine whether persons with negative urine cultures are less likely to have pathogenic bacteria on the skin.

For those persons who have negative urine cultures initially, the percentage who remain negative at the next annual evaluation will be compared for each type of bladder management.

A prospective follow-up study will be performed on hospitalized persons with SCI who develop UTI requiring treatment. Urethral and perineal cultures will be obtained just before initiation of systemic antibiotic treatment, during treatment, and 7 days after treatment. This will allow determination of the effect of systemic antibiotics on skin flora.

PROGRESS—The first patient was enrolled March 1997. We have developed a syllabus and data collection instruments, finalized project entry criteria, and trained a data collector. To date, 14 patients have been enrolled in the study, none of whom experienced any adverse effects.

[300] IMPROVING TISSUE VIABILITY OF PARALYZED MUSCLE USING NEUROMUSCULAR ELECTRICAL STIMULATION

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PURPOSE—Pressure sores are a major secondary complication of spinal cord injury (SCI). They are extremely expensive to treat and often require long periods of bedrest or surgery for successful healing. The purpose of this study is to investigate new techniques for addressing the underlying causes of pressure sores. Neuromuscular electrical stimulation (NMES) can change the characteristics of paralyzed muscles to improve their long-term response to loading, especially while seated in a wheelchair. The objectives of this study are therefore two-fold. First, it will determine the effects of exercise with electrical stimulation on the tissue viability of the skin and underlying muscle most susceptible to pressure sores. Second, it will determine the efficacy of using electrical stimulation to alter the pressure distribution under the buttocks dynamically while sitting.

METHODOLOGY—Five individuals with histories of chronic and recurrent pressure sores will be enrolled in the study. Subjects must be pressure sore free at the time of participation. Since the primary site for pressure sores is the buttock region, NMES will be applied bilaterally to the gluteal muscles. Chronically indwelling intramuscular electrodes with percutaneous leads developed at Case Western Reserve University and the Cleveland VA Medical Center will be used with an externally programmable stimulator. Following implantation, a baseline period without stimulation will yield control data for comparison to the post-treatment phases. Subjects then undergo an intensive exercise program with NMES, during which time progressive changes in muscle bulk and blood flow are monitored using computerized tomography (CT) scans and transcutaneous oxygen measurement. These assessments are indicative of the health, or viability, of the skin and muscle and will gage the effects of exercise alone on pressure sore formation. Changes in weight distribution both over the long-term (due to alterations in the intrinsic muscle properties) and over the short-term (due to active muscle contractions) will be assessed using interface pressure measurements. After reconditioning with NMES, seated pressure distributions will be recorded during slowly varying weight shifts produced by stimulated contraction of the gluteal muscles. The location and magnitude of high pressure regions will be monitored to determine the effectiveness of dynamic posture shifting. Finally, NMES will be withdrawn so that progressive changes after long-term use of NMES can be monitored.

PROGRESS—Initial testing on three NMES users and several candidates with active pressure sores has been completed to refine the methods and calibrate the assessment equipment. These pilot data indicate that individuals with histories of NMES use exhibited healthier skin and muscle than their counterparts with pressure sores as measured by transcutaneous oxygen values. Preliminary data also indicate that seated pressure distribution can be modified with stimulation of the gluteal muscles. These initial observations support the underlying rationale of the study.

FUTURE PLANS—Two individuals have recently agreed to participate in the investigation. Electrode implantation is scheduled for the last quarter 1997. Recruiting for additional volunteers is ongoing. This investigation should provide preliminary data on the therapeutic use of NMES for improving the properties of paralyzed muscle so that the incidence of pressure sores in people with SCI can be reduced. A larger-scale clinical trial will be designed based on the results of this pilot study.

[301] A COMPUTERIZED TECHNIQUE FOR THE ASSESSMENT OF ALTERNATING PRESSURE RELIEF INDEX

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Sponsor: *Huntleigh Healthcare plc, Luton (UK); and University College Salford, Salford (UK)*

PURPOSE—Decubitus ulcers result in unnecessary expenditure and misery to the patient. An important aspect in their prevention and treatment is the use of appropriate support surfaces, with the object of reducing pressure on the body surface. There is a great deal of interest in finding ways of assessing the possible efficacy of alternating pressure air mattresses (APAMs) and cushions (APACs). The purpose of this project was to develop equipment and software to provide an effective and efficient technique for the assessment of performance criteria of alternating pressure or dynamic support surfaces.

METHODOLOGY—The action of a dynamic support surface is time varying, and therefore it is important that any pressure relieving 'performance' indicator take this factor into account. A computerized system has been developed, which continuously measures the air pressure (AP), interface pressure (IP), and pressure-time cycle characteristics of alternating air mattresses and cushions. The system provides a mouse and keyboard-based, graphically oriented interface. The parameter of interest is pressure relief (PR) defined as a percentage of the cycle. This allows like-for-like comparisons to be made choosing any arbitrary common multiple of the cycle times, such as, 1 hr requires six 10-min cycles or five 12-min cycles. The pressure relief index (PRI) at any given IP threshold is defined as: the length of time (min) IP remains below the chosen threshold in 1 hr, divided by 60.

PROGRESS—Since the project began in early 1994, we have evaluated six APAMs and five APACs. This has given us a better understanding of their advantages and limitations. From the experience gained, we have also implemented several changes to the original computer program, test procedures, and pressure threshold values. In the case of APAMs for PRI calculations as a percentage of the cycle, the IP thresholds are set at 30, 20, and 10 mmHg; and for APACs the thresholds are 60, 45, and 30 mmHg.

RESULTS—Measurements of IP and pressure-time cycle indicated significant differences ($p<0.001$) between products, showing some devices were only capable of momentarily relieving pressure. Results also indicated that PR was sensitive to the design of the support system, principally air pressure, cycle time, and inflation sequence. The APAMs included in the investigation were capable of providing very low or near zero interface pressures at the sacrum only. However, the corresponding PRI values were better in the case of a mattress that reacted to changes in posture and weight of a subject.

FUTURE PLANS—Performance measurements such as PRI can be extremely useful in looking at differences between APAMs APACs, but only to indicate relative merit with respect to pressure relief. Ultimate performance is only measurable via controlled clinical trial and assessment of the many other important parameters such as comfort, ease of use, cost, maintenance, and long-term reliability. We are continuing the investigation to assess the relationship between PRI, skin tissue perfusion, and clinical outcome. Through such exercises, the true validity of performance measurement tools will become evident.

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[302] A STATIC HEEL-CUSHION CONTACT MODEL USING FINITE ELEMENT ANALYSIS

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PURPOSE—Pressure sores are common clinical problems for debilitated persons and for those with insensate skin. Once developed, pressure sores become very costly and labor-intensive to manage. Prevention is therefore essential, especially in the managed-care era when the health care dollar is tightly regulated. An optimal cushion design is perhaps the most effective means of prevention. However, since many factors govern the effectiveness of the cushion for pressure relief, designing an adequate cushion has been a process of trial-and-error and its outcome has been often unpredictable. Pressure sores are believed to be caused by excessive internal tissue compressive and shear stresses, which cannot be measured clinically. We developed a computer model simulating a static heel-cushion contact using finite element (FE) analysis. With the model, we hope to predict internal tissue stresses that may be used to optimize cushion design.

METHODOLOGY—A mathematical model was developed using FE analysis software, MARC/MENTAT (MARC Analysis Research Corporation, Palo Alto, CA). T1-weighted MR images of a supine unloaded heel were taken in discrete axial slices by placing a surface coil directly beneath the heel. The cross-sectional images were then manually digitized into nodes using NIH Image software. The nodes from the two-dimensional (2-D) axial images were then meshed with eight-node 3-D elements to reconstruct the heel geometry. The calcaneous bone was modeled as a near-rigid, linear, isotropic material (Young's modulus (E)=1700 kPa, Poisson's ratio (p)=0.1). The skin and subcutaneous tissue were modeled both as a linear isotropic (E=15.2 kPa, p=0.49) and as a homogeneous Mooney material (literature-reported) properties. A rigid flat surface (E=2000 kPa, p=0.1) and a firm foam cushion (linear isotropic, E=100 kPa, p=0.1) were both used as contact surfaces. The static loading condition was estimated to represent the total gravitational load of the foot in a supine position, and applied to the finite element model in small increments.

PRELIMINARY RESULTS—Locations of maximum tissue stress were sensitive to soft tissue and cushion material properties. Soft tissue with the linear isotropic model created the maximum compressive stresses near the calcaneous-soft tissue interface. On the other hand, soft tissue with the Mooney model created the maximum compressive stress at near the heel-cushion interface. Presence of foam cushion helped to reduce maximum internal tissue stresses in both cases. All models failed to converge at high static loads. The stress distribution predicted by the Mooney models seemed unlikely.

IMPLICATIONS—Soft tissue models used for simulation are sensitive to internal tissue stress distributions. Clinical measurements of *in-vivo* tissue properties are essential in developing an accurate soft tissue model.

FUTURE PLANS—We plan to verify tissue strains using MRI for cases involving both heel-rigid surface and heel-cushion contact. Interface pressures will be verified by direct measurement. An optimization scheme will be developed to help design the cushion. In addition, better material properties for the soft tissue needs to be further investigated.

B. Fracture Healing

[303] A NEW BIOELECTRIC METHOD FOR EARLY DIAGNOSIS OF DELAYED FRACTURE HEALING

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A623-2RA) and Health Future Foundation, Creighton University, Omaha NE 68178.*

PURPOSE—We seek to develop a procedure of skin-surface measurements of endogenous electricity for the early identification of delayed healing fractures.

METHODOLOGY—This project is designed to test the following hypothesis: normal and delayed healing fractures have distinct electrical signatures, represented by different temporal patterns of skin-surface electrical activity during the first 8 wks after a fracture. The skin-surface voltages are measured over the fracture site within 24 to 48 hrs of initial treatment. These measurements are repeated at 1, 2, 3, 4, 6, 8, 12, 16, and 24 wks after the first measurement. The patient measurements show a change in the voltage magnitude over the course of the study. The data from each patient are statistically analyzed and graphed to see if the voltage pattern revealed follows the voltage patterns seen in a previous canine study. The data are categorized as following either a normal healing (NH) or a delayed healing (DH) model. Patient charts are checked at 4 months after the initial treatment to determine whether the fracture was clinically judged by the orthopaedic surgeon to be a NH or DH fracture. Finally, a correlation between the analyzed data and the clinician's determination is made to determine validity of the hypothesis. Only patients with long bone fractures treated at the Creighton University Medical Center (CUMC) and Omaha VA Medical Center are included in the study. Instrumentation and procedure for bioelectric measurements are as described previously for the canine study, except that miniature EKG-type Ag/AgCl electrodes are used. The relationship of the voltage magnitude and time, compared to the healing time (T), is analyzed to develop indices that represent electrical signatures for NH and DH groups.

PROGRESS—Twenty-six persons have been enrolled so far, all at CUMC. These consist of 18 males and 8 females with an age range of 10 to 91. The distribution according to the type of bone is as follows: 12 femora, 7 tibiae, 2 tibiae/fibulae, 3 humeri, 1 radius, 1 ulna. The protocol is in progress for 8 subjects. Among the 18 other subjects, 8 were available for only 4 visits or fewer. The data collected so far are being analyzed and correlated with the clinician's reports to discern patterns that will allow us to establish universal characteristics of normal healing fractures, if any, regardless of age, sex, type of bone, and type of fracture treatment. In the long term, we expect to distinguish characteristics of NH and DH fractures using the aforementioned variables. We currently have two subjects who have been determined by the clinicians to have DH fractures, which have displayed distinctively different voltage patterns from those of the NH fractures. The number of subjects is still too low to make a definite conclusion on whether or not the hypothesis is valid.

[304] STIMULATION OF BONE HEALING USING BONE-MATRIX-RELATED BIOMATERIALS

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A2022-2RA).*

PURPOSE—We are evaluating the efficacy of selected biomaterials that are structurally related to bone matrix or one of its macromolecular components, with or without an autologous bone marrow graft, for achieving a complete repair of large bone defects and delayed unions.

METHODOLOGY—The experimental model for normal healing in this research is a 2 mm segmental defect in rat fibula grafted with a 5 mm long demineralized-bone-matrix (DBM) cylinder made from an allogeneic animal. Compared to this model, segmental defects 4 mm or longer grafted with a normal or inactivated DBM cyliner demonstrate varying degrees of delayed healing. Inactivation involves removal of osteoinductive proteins from DBM by a trypsin digestion method, extraction with guanidine HCl, or a combination of the two methods. These defects were treated with the following bone-matrix-related osteoconductive biomaterials: 1) DBM powder of particle size [Lz]100 µm (DBMP) and DBMP subjected to trypsin digestion (tDBMP) or guanidine HCl extraction (gDBMP); 2) methylcellulose gel (MCG) that is structurally related to collagen; 3) microcrystalline hydroxyapatite (MHA) similar in crystallite sizes to the amorphous fraction of hydroxyapatite in bone; and 4) chitosan, which is structurally related to glycosaminoglycans in the mineral-bound proteoglycans in bone. The treatments will be applied immediately after creating the defect and injected through a predrilled hole in the DBM cylinder at 3 wks after creating the defect. The outcome of treatment is evaluated at 7 wks postsurgery by measuring the bending rigidity of the fibula and the bone mineral content of the repair tissue.

To understand the cellular mechanisms that govern the healing process in the presence of the these biomaterials, the following osteogenic markers are measured at various time points during healing: DNA synthesis, DNA content, and bone-liver-kidney type alkaline phosphatase (ALP) activity (4 days postsurgery); ALP, osteocalcin and collagen types I, II, and X (2 and 5 wks); rigidity and bone mineral content (3 and 5 wks).

PROGRESS—In preliminary studies using 400–425 g Sprague-Dawley rats, we found that at 11 wks postsurgery, the mean bending rigidity of fibulae with 4 mm defects grafted with normal 7 mm DBM cylinders approached the value for fibulae with 2 mm defects grafted with 5 mm DBM cylinders (~25 N/mm). We investigated whether the healing of the 4 mm defects can be accelerated by treating them with the various osteoconductive biomaterials to attain this rigidity at 7 wks.

RESULTS—MHA treatment of fresh 4 mm defects resulted in a 21 percent increase in rigidity over untreated controls at 7 wks postsurgery, but this difference was not statistically significant. Treatments with DBMP, tDBMP, gDBMP, MCG, and chitosan resulted in 14 to 35 percent decrease in rigidity. Injection of chitosan or MHA into the defect 3 wks postsurgery also failed to accelerate bone repair. We hypothesize that there were too few osteogenic cells in the defect to benefit from the osteoconductive properties of these biomaterials. Therefore, the biomaterials, which filled the defect, proved to be barriers to new bone formation.

FUTURE PLANS—The segmental defects in rat fibula will be treated with the combination of each biomaterial and autologous bone marrow, the latter providing a supply of osteogenic cells. Concurrent experiments will involve measurement of osteogenic markers to allow a description of the sequence of cellular events involved in the success and failure of the bone repair process in the presence of osteoconductive biomaterials.

C. Other

[305] A PROSPECTIVE STUDY OF PLANTAR FOOT PRESSURE AND DIABETIC FOOT ULCER RISK

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420 (Project #A318-5RA)*

PURPOSE—We are conducting prospective research designed to identify risk factors for foot ulceration associated with diabetes, examining the independent contributions of foot deformity, macrovascular and microvascular disease, peripheral neuropathy and behavioral factors on the risk of developing a diabetic foot ulcer.

METHODOLOGY—Eligible subjects are enrolled in an internal medicine clinic, and meet the criteria for diabetes mellitus by physician diagnosis or treatment with hypoglycemic medication or insulin. Subjects who participate are assessed for the presence of suspected risk factors grouped into four categories: circulation, neuropathy, foot deformity, and self-care behaviors. Circulation factors include lower extremity Doppler blood pressures, toe blood pressures, transcutaneous oximetry, laser Doppler flowmetry, arterial pulse palpation, venous filling time, and capillary refill time. Neuropathy measures include monofilament testing, bioesthesiometry, deep tendon reflexes, intrinsic muscle atrophy, and cardiovascular reflexes reflecting autonomic neuropathy. Foot deformity measures include clinical examinations, posture and gait assessments, joint ankle measurements, and Harris mat and F-Scan testing for abnormal pressure points. Behavioral factors assessed include type of foot wear, diabetes history and control, foot self-care practices, and visual acuity. All subjects receive yearly repeat examinations and a mailed questionnaire on a quarterly basis asking them to report the occurrence of ulceration. We compare rates of outcome occurrence (incidence) by exposures of interest to determine which particular factors are related to risk of diabetic foot ulcer.

PROGRESS—To date we have enrolled 977 diabetic subjects from the Veterans Affairs Puget Sound Health Care System, Seattle Division, general internal medicine outpatient clinic.

PRELIMINARY RESULTS—We prospectively categorized 730 subjects for their risk of developing diabetic lower extremity complications by two standard risk stratification schemes. We found that one provided no information on the risk of foot complications and subjects categorized as high risk by the other had a risk of these complications only slightly higher than their average pre-test risk. Multivariate logistic regression analysis identified five clinical factors predictive of diabetic foot ulceration and five clinical factors predictive of amputation. When all five factors are present the probability of a foot ulcer is 68 percent and the probability of an amputation is 84 percent.

Results from an analysis predicting diabetic foot ulceration by a tree structured analysis of prospective survival data were presented at the 16th International Diabetes Federation, Helsinki, Finland, 1997. The classification tree incorporating demographic, historical, and examination variables shows that individuals at highest risk for foot ulceration are those insensate to the 5.07 monofilament, who have a history of amputation, and a glycosylated hemoglobin greater than 13.7 percent at entry to the study. Those who were sensate and did not have a self-reported history of peripheral vascular disease were at lowest risk. Subjects who were sensate to the 5.07 monofilament but had a history of peripheral vascular disease were at increased risk, while those who were insensate without a history of amputation had intermediate degrees of risk depending upon the presence of an orthostatic blood pressure decrease greater than 31 mmHg, the presence of hallux limitus, and poor vision.

FUTURE PLANS/IMPLICATIONS—We continue this prospective cohort study of subjects with diabetes, being followed prospectively for development of a full-thickness cutaneous foot ulcer. Extended follow-up will allow us to identify risk factors for diabetic foot ulceration. The findings to date related to risk factors for foot ulceration should be viewed as preliminary. It appears that plantar pressure, sensory and autonomic neuropathy, and skin oxygenation will be important in the pathogenesis of diabetic foot ulceration. Final analysis will provide additional information concerning risk factors for diabetic foot ulcer and potential means for prevention.

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[306] PROBLEM-SOLVING SKILLS TRAINING IN THE TREATMENT OF PRESSURE ULCERS

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PURPOSE—Pressure ulcers are a largely preventable secondary complication following SCI. Prevention requires appropriate behavior on the part of the individual and/or caregiver, namely the use of appropriate seating, proper transfer techniques, frequent pressure relief maneuvers, and the like. Despite extensive education of persons with SCI, centers treating them see some of them return with pressure ulcers that require surgery or prolonged bedrest in the hospital. Unique behavioral interventions that have promise for improving compliance, and therefore the prevention of repeat ulcers, are badly needed. Prior work has demonstrated that problem-solving skills can be learned, retained, and applied in everyday situations. The focus of this project is to evaluate the efficacy of problem-solving skills training for the prevention of skin rebreakdown in persons with SCI who are hospitalized following pressure ulcer surgery or who are on prolonged bedrest for pressure ulcer healing.

In this study we propose to test the effectiveness of a problem-solving skills training intervention for pressure ulcer prevention in terms of the following criterion measures: the degree of self-perceived responsibility for health care and maintenance; the degree of psychosocial impairment secondary to disability; general problem-solving skills; demonstrated ability to solve problems specific to skin care and maintenance; demonstrated compliance with pressure relief maneuvers; and the prevalence of skin rebreakdown following discharge. We shall also develop and disseminate materials documenting the effectiveness of this intervention and methods for implementation in other agencies by a variety of professionals.

METHODOLOGY—Potential participants in this study will be randomly assigned to either a problem-solving skills training group (training) or a no-treatment group (control). Randomization will be stratified by neurologic level of injury (paraplegia/tetraplegia) to ensure comparability of the two groups. After randomization, those who consent to participate and are assigned to training will be administered an initial battery of measures prior to intervention. They will complete the initial battery again after intervention to assess possible changes. Those assigned to control will be given the pretest battery and then administered the posttest battery 2 wks later. Both groups will be further evaluated at 6 wks postdischarge and during their next annual follow-up visit.

PROGRESS—Thirteen training and 28 control subjects have completed the initial battery. Of those, 11 training and 22 controls completed the 10-day follow-up; 6 training and 12 control subjects also completed the 6-wk follow-up; and 3 training and 8 controls have also completed the 1 year followup. Two subjects refused to participate; three training subjects are to be reimbursed.

FUTURE PLANS—We had originally anticipated enrollment of 34 controls group and 34 participants in the training group by this time. We have encountered considerable problems with recruitment and retention of participants owing to changes in hospital and department practice that have now limited the number of patients available for recruitment and participation, and to the fact that many patients are indigent and unable to procure reliable transportation back to the outpatient followup appointments.

To improve recruitment and participation we have made arrangements with plastic surgery to meet with patients admitted for skin flap repair and see them following surgery in other hospital units. Secondly, we now offer a $150 stipend to all participants who agree to be in the study. We continue to recruit exclusively for the training group so that we can have comparable numbers for the data analysis.

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XVII. Functional Outcomes

[307] TEAM CHARACTERISTICS AND PATIENT OUTCOMES ON VA REHABILITATION SERVICES

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PURPOSE—The purpose of this 3-year multisite study is to investigate the relationship of team characteristics to outcomes on VA inpatient Physical Medicine and Rehabilitation Services (PM&RS). Comprehensive measures of team, hospital, and client characteristics will be studied in relationship to functional outcomes as measured by the Functional Independence Measure (FIM).

METHODOLOGY—Approximately 52 inpatient rehabilitation teams that subscribe to the FIM are participating in the study. These hospitals represent practically all (>95 percent) VA hospitals with inpatient rehabilitation services. Project staff conduct a 1-day visit at each hospital to administer questionnaires and interviews concerning team functioning and organizational culture. FIMs, and hospital descriptive data are being obtained from archival files at PM&RS Headquarters. Team questionnaire data will be merged with client data and with descriptive organizational data and appropriate analyses conducted.

PROGRESS—Twenty-eight of the 52 data collection sites have either been completed or are scheduled in the near future. The remaining sites are in various phases of the VA R&D and University IRB research approval processes. Preparations are being made to download archival data from PM&RS Headquarters.

FUTURE PLANS—Rehabilitation teams are cost- and labor intensive. We plan to use the results of this study to develop cost-effective rehabilitation services by identifying those aspects of team functioning that are associated with good outcomes. Results will provide direction for training that will best enhance the teams' unique contributions to patient recovery, and aid in the development of integrated systems of care.

[308] LONG-TERM STRENGTH TRAINING AND FUNCTIONAL STATUS IN OLDER ADULTS

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PURPOSE —This 3-year study is designed to investigate the effects of a 2-year muscle fitness program (strength and flexibility training) on four groups of 30 older participants each. The groups are composed of controls who receive the strength training intervention (TYPICALEX), controls who continue regular lifestyle patterns (TYPICALREG), diabetics who receive the exercise intervention (DIABEX), and diabetics who continue their regular lifestyle patterns (DIABREG).

METHODOLOGY—A repeated measures experimental design is being employed in this study. Outcome measures include muscular strength and endurance, body composition, muscle mass, flexibility, functional status, exercise adherence, and quality of life. We are recruiting volunteer controls (age 65–85) for TYPICALEX and TYPICALREG and diabetic volunteers (age 50–70) age) for the DIABEX and DIABREG samples.

Muscle strength and endurance will be measured by a Chattanooga KIN-COM Isokinetic System and for one repetition maximum (1RM) on a Nautilus multi-station system. Balance will be evaluated by a Neurocom Equitest Dynamic Posturography device. Body composition will be assessed using a Harpenden skinfold caliper which has a measurement scale precision of 0.2 millimeters (mm). Muscle mass will be estimated from circumferences and skinfolds. Flexibility will be assessed using a goniometer which measures the actual range of motion for each specific joint. A modification of the Physical Performance Test (PPT) will be used to assess functional ability.

The 1-hr (50 min strength training, 10 min flexibility exercises) training sessions will be held 3 days a week for the first 6 mo, and at least twice weekly thereafter. The subjects will complete three sets of 8–12 repetitions at each of 50, 60, and 70 percent of their 1RM. Subjects will be measured at 6-mo intervals during the training interval.

PROGRESS—The project is well underway, with the recruitment process in full force and data collection progressing. Thirty TYPICALEX and 15 DIABEX have completed pre-testing and are presently training; some have completed their initial 6-mo evaluation. Ten 10 TYPICALREG and 10 DIABREG have completed initial testing.

PRELIMINARY RESULTS—Initial results show that the subjects are increasing in strength following the strength training intervention.

[309] A STUDY OF VA STROKE REHABILITATION SERVICES AND PATIENT OUTCOMES

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PURPOSE—We seek to determine whether there are differences in patterns of stroke rehabilitation services, and, if so, whether these different patterns result in different client outcomes.

METHODOLOGY—We sampled all 166 VA facilities present in FY 1995, some of which did not have pertinent data, resulting in a final sample size of 161. We identified 12,626 veterans discharged from a VA hospital between June ’95 and May ’96 with either an ICD-9-CM code for acute, non-hemorrhagic stroke with a primary diagnosis (DXLSF) of ICD-9-CM 430-432, 434, 436; a DXLSF for rehabilitation (ICD-9-CM code V57) plus a secondary diagnosis related to stroke or late effects of stroke (ICD-9-CM 433, 435, 437, 438, 342); or a DXLSF of transient ischemia (ICD-9-CM 433) or occlusion/stenosis of the precerebral arteries (ICD-9-CM 435) plus a secondary stroke-related diagnosis (ICD-9-CM 342, 430-432, 434, 436).

We looked at such predictor variables in rehabilitation settings as systemic structure, personnel, and physical setting for care, defined according to resources and organization; among the veterans we considered age, race, comorbidity index, and use of a feeding tube, Foley catheter or intubation during the index hospitalization; and we considered the teaching status, referral center, and acute care resources (e.g., ICU, physician specialists) among the facilities. As outcome variables, we considered the discharge destination from acute care; the length of stay in acute care; the number of readmissions following discharge from acute care; and mortality at 6 months.

We obtained our data from facility surveys (acute care in 1994-95 and rehabilitation in June 96), from computerized data sources both inside the VA (PTF and PAID Data Bases) and outside the VA (Uniform Data System, UDS-MR); and from VA administrative sources (e.g., listings of special programs). The rehabilitation survey was based on our conceptual model for rehabilitation services; questions were developed in collaboration with expert clinicians and researchers; it was piloted at four VA medical centers diverse in volume of acute stroke patients, in organization and resources for rehabilitation, and in geographical location. We conducted beta testing at the eight medical centers in VISN 6.

We reduced the data by eliminating variables with bad or unreliable data, duplicate data, or high levels of missing data; by identification of marker variables (within categories of variables, markers variables were selected using physical therapists at the rehabilitation provider level and physiatrist at the physician/facility level); and by summarizing across selected categories of variables at the rehabilitation provider and facility level. The variables remaining will undergo factor/cluster analysis. Identified factors/clusters will be reviewed against our original conceptual model and by an expert panel, who will help weight variables for summary scores and select marker variables for each cluster. Bivariate analyses with our outcomes will be done for potential marker variables. The final summary scores and marker variables will then be analyzed in separate multivariable regressions, which will examine their relationship to patient outcomes while controlling for patient and facility characteristics.

PROGRESS—Data collection, entry, cleaning, and reduction are complete.

PRELIMINARY RESULTS—Our acute care survey is 98 percent complete; our rehabilitation survey is 100 percent complete. We have found a substantial variation in rehabilitation resources nationwide. For example, average rehabilitation workloads varied from 755 units per physical therapist (PT) in the South to 362 units per PT in the West. Tuition support provided to rehabilitation was greater in academic VAs ($6,839) than in in nonacademic VAs ($3,223). Similarly, 60 percent of rehabilitation bed units in academic VAs always or almost always had adaptive toilets in patient rooms compared to 25 percent of those in nonacademic VAs.

FUTURE PLANS—We shall complete the data analysis outlined above and disseminate results.

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[310] DEVELOPING DEPARTMENT OF VETERANS AFFAIRS REHABILITATION-RELATED GROUPS: A PILOT STUDY

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Sponsor: *Department of Veterans Affairs, VA Rehabilitation Research and Development Service, Washington, DC 20420*
(Pilot Project #B2063-PA)

PURPOSE—We seek to compare stroke and orthopedic patients' lengths of stay (LOS) in VA Medical Center (VAMC) inpatient rehabilitation units to those of the private sector after accounting for case mix differences, in order to determine how VAMC rehabilitation inpatients differ from those treated in the private sector. By so doing, we hope to address the need for a rehabilitation case mix measure specific to the VAMC.

METHODOLOGY—An expert panel of rehabilitation clinicians developed hypotheses on how patients with stroke and orthopedic conditions presenting to VAMCs differed from those presenting to private sector facilities. These hypotheses were tested through the development of multiple linear regression models on the logarithm of LOS (ln LOS) using Functional Independence Measure (FIMTM) data from the Uniform Data System for Medical Rehabilitation (UDSMRTM). Case-mix adjustors included the Functional Independence Measure-Function Related Groups (FIM-FRGs) along with other clinical factors. To explore need for a VAMC-specific patient classification scheme for inpatient rehabilitation, a set of VAMC-specific measures for stroke and orthopedic rehabilitation were developed and compared to private sector FIM-FRGs. The methods of development, based on recursive partitioning, paralleled those used to establish the FIM-FRGs. The VAMC-specific classification is referred to as the Rehabilitation-Related Groups (RRGs).

RESULTS—LOS in VAMC inpatient rehabilitation is nearly twice that of the private sector. As initially hypothesized, the VAMC, compared to the private sector, treats higher proportions of clients with traits associated with longer LOS, including being single, separated or divorced, unemployed or retired due to disability, being Black, and having a longer onset-to-admission interval. Even after adjustment for these case mix differences, LOS in the VAMC was longer. The RRGs, developed from the records of 5,435 clients discharged from the VAMC in 1994 and 1995, explained 15.1 and 9.5 percent of the variance in ln LOS for stroke and orthopedic patients, respectively. The RRGs defined two severity groups within the stroke and two groups within the orthopedic categories that distinguish between those with greater and lesser physical disabilities. Mean LOS for the functionally severe VAMC stroke subjects with admission motor-FIM scores less than 57 was 39.3 days, while it was 23.9 days for the functionally less severe group. Mean LOS on VAMC inpatient rehabilitation services for the functionally severe orthopedic group with admission motor-FIM scores less than 56 was 32.0 days, while it was 20.3 days for the less severe group.

In contrast to RRGs, FIM-FRGs assign stroke subjects to nine and orthopedic subjects to 13 groups. The FIM-FRGs explained 17.4 and 14.5 percent of the variance in ln LOS, respectively, for stroke and orthopedic subjects undergoing rehabilitation in the VAMC.

CONCLUSIONS—Once calibrated to reflect VAMC utilization patterns, use of the FIM-FRGs compared to RRGs would provide more detailed clinical profiles and facilitate direct comparisons of VAMC to private sector rehabilitation services. With regard to explanatory power for LOS, the FIM-FRGs would have a slight advantage over the RRGs within the VAMC. This minimal predictive advantage would occur at the expense of greatly increased complexity of the predictive algorithms. In contrast, the greater parsimony of the RRGs would reduce administrative burden in any systems of centralized monitoring or budget allocation. Because of their extreme simplicity, the RRGs would likely contain sufficient numbers of cases in each group for meaningful statistical comparisons, thus facilitating risk adjustment quality improvement efforts, even in the smaller bed units. Choice of RRGs over FIM-FRGs for use in the VAMC depends on the application and analytic objects.

[311] DEVELOPMENT OF A SYSTEM TO AID ORTHOPAEDIC SURGICAL DECISION-MAKING IN CHILDREN WITH CEREBRAL PALSY THROUGH PREDICTION OF POST-SURGICAL GAIT PATTERNS

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PURPOSE—In order for the best possible outcome of surgery in cerebral palsy (CP) to be realized, there is a need for physicians to have objective criteria by which to analyze walking patterns and decide on the type of intervention for individuals. The purpose of this project is to develop a computer software tool that would be used to assist surgeons in planning orthopaedic surgery specific to CP to give them the ability to predict the results of their surgery through seeing simulated walking patterns prior to surgery.

METHODOLOGY—The approach to solving this problem is through two steps: the simulation of walking for a given input signal, and the synthesizing of new input signals, based on historical data. In order to simulate walking, it is necessary to collect system input (muscle electromyographic signals) and system output (movement patterns) for various subjects. An adaptive controller will be developed to derive realistic time-varying muscle force patterns that will drive a biomechanical model (in software) to replicate recorded movement. This will be done through developing the software model with appropriate lower-level (spinal cord) sensory feedback loops, a realistic optimization rule based on the input data, and the use of adaptive artificial neural network controller methods to arrive at the control patterns. Once realized, the operator will be able to provide starting conditions and a muscle profile pattern, and derive movement of the biomechanical model.

A second component will focus on surgical outcome. A database of surgical subjects (pre- and post-operative), containing motion analysis data, muscle activation data, and measures of subject spasticity and range-of-motion will be developed. A model will be developed to determine transformations of muscle-activation patterns before and after surgery. This will provide a means of predicting how a muscle-activation pattern may be changed due to a particular surgery. Once developed, this model could be used in combination with the movement model to predict post-surgical movement patterns for children with CP.

PROGRESS—This project is just beginning.

[312] DEVELOPMENT OF CLINICAL PROTOCOLS BASED ON ERGONOMICS EVALUATION IN RESPONSE TO AMERICAN DISABILITY ACT OF 1990

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PURPOSE—We are working to develop a series of models that could be used in the process of employment and rehabilitation of injured workers under the ADA. More specifically, the goal is to develop models that can successfully predict the requirements of industrial tasks. These models would be used for both analysis and simulation purposes. Once these models are validated, they could be used with documentation of subjects' functional capabilities to prescribe job-specific rehabilitation programs and/or assistive devices, that would enable individuals to perform the essential functions of the job.

METHODOLOGY—The requirements of a task have often been quantified in terms of the motion and forces needed to complete it. An often neglected aspect is that in many cases it must be performed repetitively over the duration of a shift. Hence, the maintenance of the forces and motions over an extended period of time must also be considered. Therefore, a goal of the employment or rehabilitation of a disabled worker is to make sure that a given task can be performed not once, but for the entire duration that the job requires.

The development of models that can predict the endurance, as well as assess the degree of fatigue in workers, has been a major focus of this project. Because the threat of pain or injury necessarily prevents the performance of maximal exertions by injured workers, it is important to develop the clinical protocols and models using data from submaximal exertions. Once the models are validated, the ability to predict the endurance based on the performance of relatively few submaximal exertions will be possible. The attributes of our developed protocols are enormously important, since the employer may not be able to inquire about prior or existing disabilities of the prospective employee. The use of submaximal exertions reduces the risk of reinjury to the applicants/injured workers.

PROGRESS—We have developed several testing protocols for the quantification of trunk muscle strength and endurance during diverse sets of fatiguing submaximal tasks: constant torque isometric exertions; sustained varying torque isometric exertions; repetitive dynamic lifting and lowering exertions; isokinetic single-joint testing to generate 3-D dynamic strength responses as a function of joint angle and velocity; and quantification of kinematic and kinetic data variability during multilink coordinated manual material handling task.

Another experiment was performed in order to simulate a greater number of industrial conditions that include dynamic repetitive exertions. Sixteen nonimpaired male controls were recruited to perform repetitive dynamic trunk extension exertions at two relative torque levels and two repetition rates. Doubling the repetition rate to 10 per min caused a greater decrement in the endurance time than doubling the relative torque output to 70 percent. Hence, workers returning to their job may benefit from activities that have low repetitions. The findings also reflect the need to stress the acquisition of endurance during the rehabilitation.

Models are being developed to predict the endurance time based on parameters obtained from the noninvasive surface EMG of the trunk extensor muscles. Both short-time Fourier transform and wavelet transform techniques are being used to process the EMG.

Biomechanical simulation models provide a time and cost effective tool for answering "what-if" questions. A computer-based simulation program of multilink coordinated lifting that predicts the optimum motion pattern(s) required to perform a wide range of lifting tasks subjected to constraints based on experimental strength profiles has been developed.

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[313] COMORBIDITIES AND COMPLICATIONS IN STROKE: INCIDENCE, RISK FACTORS, AND EFFECTS ON OUTCOMES

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PURPOSE—Individuals who sustain a stroke may be as disabled by the consequences of associated medical conditions as by the stroke itself. This study is designed to investigate clearly and systematically the incidence, risk factors, and impact on rehabilitation outcomes of preexisting conditions and medical complications of stroke.

METHODOLOGY—Data have been collected on the 1,340 patients admitted to the inpatient stroke rehabilitation service from December 1993 through May 1997. Demographic, stroke, medical comorbidity, and other information has been collected on 1,201 patients and entered into the database. Laboratory results and data on secondary complications have been reviewed for 1,000 of those patients. Impairment disability measures have also been collected on these same 1,000 patients.

PROGRESS—The most common preexisting complications found in our stroke population to be hypertension, a history of smoking, and diabetes. Other preexisting complications of clinical significance include coronary artery disease, myocardial infarction, congestive heart failure, and atrial fibrilliation. The most frequent complications developed during the acute hospitalization were urinary tract infections, pneumonia, hypertension, pressure sores, seizures, and anemia. The most common complications developed during acute inpatient rehabilitation include urinary tract infections, joint and soft tissue pain, electrolyte abnormalities, and depression. It is significant that 25 percent of stroke survivors seen for acute inpatient rehabilitation did not develop any secondary medical complications. Information from routine laboratory tests also has been collected. Almost one-third of patients have low serum albumin on admission to rehabilitation and that 38 percent have low levels of hemoglobin.

[314] DEVELOPMENT OF CLINICAL PROTOCOLS BASED ON ERGONOMICS EVALUATION IN RESPONSE TO AMERICAN DISABILITY ACT (1992)

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PURPOSE—The Americans with Disabilities Act (ADA) of 1992 ensures equal opportunity in employment for the 43 million Americans who have disabilities. Title I of the ADA prohibits employment discrimination against people with disabilities who are qualified to perform the essential functions of a job.

The objective of this project has been to develop a series of clinical protocols and biomechanical models that could be used in the process of employment and rehabilitation of injured workers given the ADA. More specifically, the goal is to develop protocols that can quantify and models that can successfully predict the functional requirements of industrial tasks and functional capacity of healthy and impaired individuals.

METHODOLOGY—The proposed novel clinical protocols are based on submaximal exertions to avoid the confounding factors of fear of injury and pain provocation that may occur during the maximum voluntary exertions that are currently used. In addition, using the parameters that are based on the spectral distribution of trunk muscle activities, we are to obtain the trunk muscle endurance capability which is significant for two reasons: 1) the ability to perform repetitive submaximal exertions of a task demand is important in the return to work or rehabilitation of injured workers; and 2) the spectral parameters of EMG may be more objective since they cannot be voluntarily controlled by the individual, as can strength, range of motion, or speed of movement.

Biomechanical models have been used for both analysis and simulation manual material handling tasks. Once these models are validated, they could be used with documentation of subjects' functional capabilities to prescribe job-specific rehabilitation programs and/or assistive devices, that would enable individuals to perform the essential functions of the job. Manual material handling tasks have been the focus of our attention due to its pervasiveness in industry, and the trunk muscles and spine were selected for the most detailed investigation due to the observation that a large proportion of ADA cases involve low back disability.

PROGRESS—We have developed the following testing protocols for the quantification of trunk muscle strength and endurance during diverse sets of fatiguing submaximal tasks: a) constant torque isometric exertions; b) sustained varying torque isometric exertions; c) repetitive dynamic lifting and lowering exertions; d) isokinetic single-joint testing to generate 3-D dynamic strength responses as a function of joint angle and velocity; e) quantification of kinematic and kinetic data variability during multilink coordinated manual material handling tasks; f) simulation of trunk motion with and without impairment; and g) development of models to predict triaxial isometric trunk strength.

RESULTS—While quantifying the trunk muscle recruitment during the isometric tasks, it was observed that as the subjects fatigued, muscles other than the primary trunk extensors became more active. The implication of this finding is that if a worker has a deficit in either the primary or secondary muscles, risk of injury may increase. Using a database of motion profiles from a manual lifting experiment, the Karhunen-Loeve Expansion (KLE) was shown to be quite effective for representing the various motion profiles, where the number of basis vectors (eigenvectors) and coefficients needed to accurately represent the data were substantially smaller than the original data set resulting in lower order space or dimension.

FUTURE PLANS—The development of several other models are planned for the upcoming year. For one, it is of interest to predict multilink coordinated lifting strength based on isolated joint strength. Twenty subjects have been tested in order to develop this model. The determination of which wavelet-based parameters are most robust in the quantification of fatigue will also be a focus. Most importantly, the validation of the models with a low back impaired population is planned for the upcoming year.

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Neuromuscular trunk performance and spinal loading during a fatiguing isometric trunk extension with varying torque requirements. Sparto PJ, Parnianpour M, Marras WS, Granata KP, Reinsel TE, Simon SR. J Spinal Dis 1997;10(2):145–56.

Spectral and temporal responses of trunk extensor EMG to an isometric endurance test. Sparto PJ, Parnianpour M, Reinsel TE, Simon SR. Spine 1997;22(4):418–25.

[315] RELATION OF REHABILITATION INTERVENTION TO FUNCTIONAL OUTCOME

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PURPOSE—A clear relationship between medical rehabilitation therapy and functional outcome has not been demonstrated. We have assumed that ''more of the right kind'' of therapy results in better functional outcomes; however, there is little objective evidence to support this assertion. Recently, employer concerns about health care cost escalation has led to efforts to reduce costs and lengths of stay. We urgently need to describe objectively what the ''right'' kind of therapy is. Cost-effective, competitive rehabilitation services will be based on a clear understanding of what resources and strategies result in the most desirable outcomes at least cost. It is the purpose of this project to objectively measure and then demonstrate relationships between therapy type and extent of functional outcomes, based on recently developed methods. Preliminary studies have illustrated the motor and cognitive recovery attained by patients undergoing comprehensive medical rehabilitation, and moderate correlations with nursing time and some billed services but not others, including occupational therapy. Further study is needed to identify relationships between impairment and disability, the extent to which rehabilitation goals are met, and barriers to goal attainment and functional recovery.

The specific aims of this 4-year study are to:

1. Document the characteristics of functional improvement during inpatient rehabilitation;
2. Describe the relationships between type, intensity, and duration of rehabilitation interventions and functional improvement;
3. Evaluate differences between persons with specific kinds of impairments in functional improvement; and
4. Describe extent and rate of functional improvement in terms of therapeutic goals and activities, barriers to rehabilitation process, and comorbidity.

METHODOLOGY—Three impairment groups were included: persons with stroke, traumatic brain dysfunction, and spinal cord dysfunction. These groups are among the largest populations served by inpatient rehabilitation programs. Data were collected from seven subscribers to the Uniform Data System for Medical Rehabilitation (Rehabilitation Institute of Chicago, Lutheran General Hospital, Mid-America Rehabilitation Hospital, Erie County Medical Center, The Institute for Rehabilitation and Research, Baylor Institute for Rehabilitation, and Long Beach VA Medical Center); a sample of 300 was collected through July 1997. Collection of follow-up data and cleaning and entry of data will continue through the year.

For each subject, Functional Independence Measure (FIM) scores were assessed weekly by nursing staff; nursing activities were collected during a 24-hr period weekly; therapy hours were extracted from bills; and therapy activities and goals, comorbidities, and barriers were summarized. An advisory identified, reviewed, and approved a list of rehabilitation goals, therapy activities and interventions, barriers to goal attainment, and comorbidities.

PROGRESS/PRELIMINARY RESULTS—In a preliminary analysis of data, a significant correlation ($r=0.36$, $p<0.05$) was found between the intensity (units/day) of occupational therapy and goal attainment in subjects who achieved between 40 and 100 percent of their goals; that is, more intense therapy was associated with greater goal attainment. There was a nearly significant relationship between length of stay and percent goal attainment ($r=0.28$, $p=0.09$) such that those with longer rehabilitation stays attained more of their goals. For specific occupational therapy goals, persons who received more intense occupational therapy were more likely to attain grooming ($p<0.02$), bathing ($p<0.03$), eating ($p<.05$), functional communication ($p<.05$), and community integration ($p<.01$) goals.

Gains in motor function as measured by the FIM were positively correlated with both the total number of occupational therapy units (r=0.43, p<.01) and intensity of occupational therapy (r=0.27, p<.05); that is, subjects who received more total occupational therapy service and more intense services (hours/day) made larger FIM-measured motor gains. Gains in cognitive function as measured by the FIM were positively correlated with total occupational therapy units (r=0.57, p<.01), but not intensity of services.

Therapists reported barriers to goal attainment using a list of 42 barriers. We used multifaceted rating scale analysis to calibrate the vulnerability of each goal to nonattainment and the likelihood of each barrier occurring. Slow neurologic recovery was the most frequently cited barrier followed by cognitive, behavioral, motivational, and emotional problems. Occupational therapy goals which were most often impeded were lower and upper body dressing, toileting, and bathing.

IMPLICATIONS—Intensity of occupational therapy was related to goal attainment for some, but not all, goals. Larger functional gains in bathing, grooming, functional communication, client-caregiver education, and community education were seen in those who received more intense occupational therapy. Improvement in cognitive function from admission to discharge and goal attainment were strongly correlated, suggesting that improvement in cognitive status may explain goal attainment. Goal setter variability may explain some of the nonsignificant relationships. Some therapists may be better predictors of potential improvement, while others may set unrealistic goals. Course of impairment reduction appears to be the rate-limiting factor in disability reduction. Dose effects of therapies are not simple and uniform. Some therapies achieve impairment remediation (particularly speech therapy), while occupational therapy achieves disability reduction. Benefits of therapy may be reflected in skills other than those which were the explicit focus of treatment. Course of impairment and disability reduction varies across impairment group. Providing the right dose of rehabilitation therapies is an art which must be described better. Ongoing work will examine the effects of comorbidities and complications on functional gains. Selecting the optimal setting for rehabilitation and therapy intensity could be guided by dissemination of the project's final results.

[316] TESTING OF POLYURETHANE FOAMS TO DETERMINE THEIR STRESS-STRAIN RELATIONSHIP

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PURPOSE—Polyurethane foam (PU) is commercially available, lightweight, easy to handle, durable, inexpensive, easily modified for body fitting, and widely used for various medical applications. PU has been used for such things as wheelchair cushioning, postural positioning, head and back support, pediatric immobilization, shoe insoles, and prosthetic limb interfaces. Institutionalized elderly and disabled individuals who sit motionless for many hours during the day are at a high risk for developing decubitus ulcers. Knowing the material properties of these foams will help in achieving the design goal of pressure relief at the human interface. The objective of this study is to investigate the mechanical properties of cushioning foam by performing compression tests on three types of PU in accordance with the American Society for Testing Materials (ASTM) standards.

METHODOLOGY—For this study, the Indentation Force Deflection (IFD) Test for both specified deflection and force are used to determine the stress-strain relationships of the PU. The IFD with specified deflection was used as a large deformation test. The foams used for this study are Fire Resistant (FR) PU, #6 PU, and PU Beige. These materials were tested according to ASTM D-3574-95, *Standard methods of* *testing flexible cellular materials—slab, bonded and molded urethane foams.* This test consists of measuring the force required to compress the foam by 25 and 65 percent of its original thickness. The IFD with specified force was used as a small deformation test. This force deflection test is determined by measuring the thickness of the foam under a force of 4.5 N, 110 N, and 220 N. The standard specifies that the test specimen must be an entire product or a suitable portion of it, with the further specification that the specimen should have dimensions not less than 380×380×20 mm. A circular indenter with a diameter of 203 mm should be used on the test specimen. Several rectangular samples (38.1×38.1×10.2 cm, 30.5×30.5×10.2 cm, 4×4×5 cm) and 10.2 cm high cylinders with a 10.2 cm radius of each material were tested with two different testing machines. Initially, stress-strain data were collected on a strip chart recorder, but in latter stages of testing, a data acquisition system was used.

PROGRESS—Data collection is complete. Analysis on the linear (small deformation) regimes of the PU's stress-strain curve is completed. Currently, analysis on the nonlinear region (large deformation) of the stress-strain curve is underway.

RESULTS—Test results varied according to the relationship between the size of the test specimen and the indenter. At large strains, the larger and medium size blocks carried a much larger stress than the cylinder and smaller block. This is partly due to the shear force between the material and the sides of the indenter for the large specimens. The effect can also be explained through the theory of elastic foundations. In this case, deflection under the indenter is a function of rotation, reaction moment, and reaction force throughout the cross-section of the foam.

FUTURE PLANS—We shall complete analysis of the nonlinear portion of the stress-strain curve.

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XVIII. Miscellaneous

[317] HOST THE 9TH INTERNATIONAL MOBILITY CONFERENCE IMC 9

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PURPOSE—An invitation was extended to Dr. Blasch at the Decatur VA Rehab R&D Center to host the 9th International Mobility Conference in Atlanta, GA in 1998. This will be the first time the IMC has been held in the United States.

BACKGROUND—The profession of Orientation and Mobility (O&M) originated at the Valley Forge Army Hospital during World War II and later moved to the Hines VAMC. Because many Americans from the Hines VABRC and Western Michigan University (WMU) were the mentors and ambassadors of mobility to other countries, they supported the advantages of professional mobility meetings. In 1979, Mr. Dennis Cory an American trained at WMU and living in Germany, established the International Mobility Conference (IMC). The following is the description of the IMC as stated in the IMC handbook: [ext]IMC is an independent group of practitioners in mobility of the visually handicapped consisting of mobility instructors and mobility centers. Its aim is furthering the level of expertise for mobility instructors through an international exchange of ideas and information.

IMC is dedicated to co-operation with all organizations of and for the blind. In organizing a regular international meeting for mobility instructors, IMC promotes and upgrades mobility services.

Even from the very beginning of the IMC, the US has always been included. The IMC began in 1979 in Frankfurt Germany. The Keynote speaker at this conference, Dr. Richard Welsh, Co-Editor of the textbook, *Foundations of Orientation and Mobility* was from the USA. Each succeeding year an individual from the US was invited to be the keynote speaker. The dates and meeting places of the IMC include:

1979: Frankfurt, Germany
1981: Paris, France
1983: Vienna, Austria
1986: Jerusalem, Israel
1998: Atlanta, USA
1989: Veldhoven, Netherlands
1991: Madrid, Spain
1994: Melbourne, Australia
1996: Trondheim, Norway

PROGRESS—The 9th International Mobility Conference will be held in Atlanta, GA July 1–6. The response from the call for papers has been overwhelming. Based on the initial review, the final program will have at least representatives from more than 30 different countries. With the large number of submissions, it is anticipated that approximately 80 percent of the presentations will be from individuals outside of the US. The first 2 days will have three concurrent seminars, including: Research in O&M, presenting the most recent research on technology and techniques for the orientation and mobility instruction of individuals who are visually impaired; Needs and Basic Skills in O&M, focusing on countries that are just beginning to introduce O&M; and Education of O&M Instructors (limited to those individuals involved in preparing O&M instructors).

The main conference will have approximately 150 sessions with a large poster session. The four keynote sessions will start with Dennis Cory (Germany) who will present some of the International factors that must be considered when listening to many of the presenters.

These factors include such things as the culture, economy, and political climate. Rick Welsh will engage Russ Williams in an informal review of the contributions of Hines VA Blind Rehabilitation Center that combined the different approaches to O&M from the Valley Forge program and the Avon Old Farms program. This first-person account by Russ Williams will provide fresh insights into the history of the development of O&M.

Erik Ostergaard (Denmark) and Stanley Suterko (USA) will present personal, unique, and sometimes embarrassing experiences they have had in establishing O&M programs in other countries. The last keynote session will feature Steven LaGrow (New Zealand) who will present some of the unique customs of several subcultures in relation to the teaching of O&M.

FUTURE PLANS—The registration materials for the IMC will go out the first week of November. It is anticipated that there will be 600–1,000 individuals attending from all parts of the world. Proceedings will be published.

[318] HEALTH BEHAVIORS IN SCHOOL-AGED CHILDREN WITH PHYSICAL DISABILITIES

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PURPOSE—Children with physical disabilities are at risk for acquiring secondary disabilities in adulthood such as heart disease, stroke, respiratory problems, social, and emotional difficulties. Some secondary disabilities can be reduced by adopting healthy lifestyles during childhood. The purpose of this research is to identify the lifestyle behaviors of children with physical disabilities and to develop health promotion initiatives for these children.

METHODOLOGY—In partnership with 16 Ontario children rehabilitation centres, we administered the same questionnaire, Health Behaviour of School-Aged Children: A WHO Cross-National Study (HBSC), as a national research project to 319 children, aged 11–16, with such physical disabilities as amputation, arthritis, cerebral palsy, muscular dystrophy, or spina bifida. We developed the required methodology for interviewing children with a variety of physical disabilities. To gain a greater understanding of the survey results, we conducted 16 focus groups with youth with physical disabilities, their parents, young adults with physical disabilities, health care professionals, and researchers.

PROGRESS—Our findings showed that lifestyle behaviors of concern to these children are: diets high in sugar and fats, lack of exercise, social isolation, and lack of access to information about relevant sexual issues. Our findings also demonstrated that these young people have some healthy lifestyle behaviors and attitudes. They are considerably less likely to smoke or drink, demonstrate no differences in self-esteem and depression, and have more positive attitudes toward parents, teachers, and school than their nonimpaired age-mates. The focus group participants offered reasons to explain our survey results. They also suggested health-promotion initiatives to maintain health-enhancing behaviors and to ameliorate health-inhibiting behaviors.

One health-promotion initiative we have achieved is the creation and production of a poster about leisure and exercise for children with physical disabilities. We collaborated with 10 young people with spina bifida and with *abilities* magazine, Canada's lifestyle magazine for people with disabilities. The poster was the centerfold pullout in the Fall 1997 issue.

FUTURE PLANS During the next year, our goal is to administer the HBSC survey to adults with physical disabilities, with revisions to the survey reflective of an adult population; to compare results of the adult survey to our previous results with children; to continue developing health-promotion initiatives aimed at reducing the prevalence of secondary disabilities; and to expand our partnerships to further our research, as well as to develop and implement health-promotion initiatives.

RECENT PUBLICATIONS FROM THIS RESEARCH

Adolescents with physical disabilities: some psychosocial aspects of health. Stevens E, Steele C, Jutai J, Kalnins I, Bortolussi J, Biggar D. J Adolesc Health 1996;19:157–64.

Lifestyle health behaviours of 11 to 16-year-old youth with physical disabilities. Steele C, Kalnins I, Jutai J, Stevens E, Bortolussi J, Biggar D. Health Educ Res 1996;11(2):173–86.

[319] RESOURCE UNIT FOR INFORMATION AND EDUCATION

Dudley S. Childress, PhD; Jan Little, MS

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Sponsor: *National Institute on Disability and Rehabilitation Research, U.S. Department of Education, Washington, DC 22202*

PURPOSE—The Resource Unit for Information and Education (RUIE) disseminates information about the general area of prosthetics and orthotics, and about the research projects conducted by the Northwestern University Prosthetics Research Laboratory and Rehabilitation Engineering Research Center, to people with amputations and other disabilities, prosthetists, orthotists, students, and individuals engaged in research.

METHODOLOGY—The mission of the RUIE is to reach a geographically wide-spread audience with many levels of interest in this area. To do this, various types of media are used, including: *Capabilities,* a quarterly newsletter with circulation of over 2,500; *Activity Report* a review of progress in research projects; *Resource Guide of Prosthetics & Orthotics* (*Guide*) is a listing of support groups, assistive technology sources, suppliers of prosthetics and orthotics, components, materials and services, related agencies; our web site (http://www.repoc.nwu.edu/) features videos of research activities, annual reports of progress in research, bibliographies of selected topics in prosthetics and orthotics, listing of publications and links to the Department of Education, Department of Veterans Affairs and other related agencies, organizations and companies; our Help Line (voice: 312/908-6524, TDD: 312/908-6526, email: reiu@nwu.edu) gives direct access to the general public; and our Consumer and Technical Advisory Panel Meetings bring researchers and clients together for valuable exchanges of information.

PROGRESS—Requests for the *Guide* have doubled over the previous year after a press release about the publication appeared in publications for vocational counselors and case managers. As a result of word of mouth, visits to our web site and other actions, the RUIE receives 3-4 requests per week for inclusion on the *Capabilities* mailing list. Over 35 requests for information are processed each month as a result of inquires through Help Lines. A new feature, "The VA Presents... News from the Department of Veterans Affairs," was initiated in the July 1997 issue of *Capabilities* with the cooperation of the Prosthetic and Sensory Aids Service, VA Chicago Health Care System, Lakeside Division. News items are solicited from all DVA personnel through Forum.VA.Gov.

RESULTS—Feedback from consumers, prosthetists, orthotists, doctors, and others indicates that the services of the RUIE are both helpful and much needed. Use of electronic media has greatly facilitated information dissemination services. Since its launch in 1995, the web site has had 65,871 visits from 82 countries.

[320] ADAPTIVE BIOLOGICAL SIGNAL PROCESSING

P.A. Parker, PhD
Institute of Biomedical Engineering, University of New Brunswick, Fredericton, NB CANADA E3B 5A3; email: biomed@unb.ca

Sponsor: *University of New Brunswick Research Fund*

PURPOSE—We are investigating the performance of adaptive matched filters and adaptive noise cancellation filters in evoked potential estimation

METHODOLOGY—In order to obtain useful somatosensory evoked potentials (SEP), signal enhancement methods must be applied in order to increase the signal-to-noise ratio (SNR). To date in this project, an adaptive matched filter has been investigated, and a SNR gain of 6dB has been found while tracking slow varying changes in the signal. In order to reduce the effects of large interfering myoelectric signals, adaptive noise cancellation filters are being studied.

PROGRESS—To date the performance equations have been derived, and the initial experimental work is encouraging. Cross-talk-resistant filters are being investigated, as well as multichannel filters. Application of these filters to stimulus artifact and ECG interference reduction in evoked potential measurements has been studied with good results. Artificial neural network implementations of the adaptive filters have proven very effective.

[321] FAILURE OF CRICOPHARYNGEAL MYOTOMY TO IMPROVE DYSPHAGIA FOLLOWING HEAD AND NECK CANCER SURGERY

John R. Jacobs, MD
Wayne State University Medical School, Detroit, MI 48201

Sponsor: *None listed*

PURPOSE—We seek to determine whether cricopharyngeal myotomy can improve dysphagia associated with head and neck cancer surgery.

METHODOLOGY—We have conducted a prospective, randomized trial in 12 clinical sites across the United States on patients undergoing combined modality therapy for squamous cell carcinoma of the tongue base and supraglottic larynx.

Intervening with cricopharyngeal myotomy on a randomized basis, we conducted videofluoroscopic examination to determine oropharyngeal swallowing efficiency. This is defined as the ratio of percentage swallowed to total swallowing time utilizing three different bolus consistencies.

PROGRESS—We followed 125 patients undergoing combined modality therapy for squamous cell carcinoma of the tongue base and supraglottic larynx between 1989 and 1994.

RESULTS—No significant difference in oropharyngeal swallowing efficiency between myotomy versus no myotomy was seen at 6 months of follow-up regardless of bolus consistency.

IMPLICATIONS—In this prospective test of cricopharyngeal myotomy, the procedure fails to significantly improve dysphagia associated with head and neck cancer surgery. The efficacy of this surgical procedure in other disease entities should be rigorously explored.

Section II
VA Sponsor Index with Selected Program Summaries

Part A: Department of Veterans Affairs

Rehabilitation Research and Development Service
810 Vermont Avenue, N.W.
Washington, DC 20420
John R. Feussner, MD
Chief Research and Development Officer
Veterans Health Administration
Department of Veterans Affairs, Washington, DC

The mission of the Rehabilitation Research and Development Service is to support an Intramural Research and Development Program for improving the quality of life of impaired and disabled veterans. This is accomplished by conducting a comprehensive program of research, development, and evaluation of existing and emerging rehabilitation technology (devices, techniques, and concepts of rehabilitation). This provides for rapid transfer of Rehabilitation R&D technology and dissemination of information into the VA medical care system, allowing for greater functional independence in the activities of daily living of disabled veterans and contributes to the nation's knowledge about diseases, disability, and rehabilitation.

Areas of special emphasis include aging, physical fitness, and psychosocial rehabilitation.

In areas of prosthetics, amputation, and orthotics, VA-sponsored researchers are continuing to test new materials and use computer technology such as CAD/CAM to develop a new generation of artificial limbs. For spinal cord injuries, the use of robotics continues to be studied, as does the possibility that computer-controlled electrical stimulation can be used to restore function to paralyzed limbs. Research projects in the area of sensory aids include the continuing development of advanced mobility aids for visually impaired people, digital hearing aids for those with hearing impairment, and various studies on treatment strategies and communication systems for aphasic individuals.

The Department of Veterans Affairs Rehabilitation Research and Development Service (Rehab R&D) sponsors a national program to review proposals submitted by researchers in the field of rehabilitation. The Rehabilitation Research and Development Service Scientific Merit Review Board and ad hoc members assess proposals for their scientific and technical merit, budgetary needs, and time requirements.

The VA Rehab R&D Program's scientific and technologic operation is located at 103 South Gay Street, Baltimore, MD 21202, which consists of the following two programmatic sections:

Technology Transfer Section
Saleem J. Sheredos, Program Manager

The Technology Transfer Section (TTS) evaluates potential products emerging from rehabilitation R&D, primarily sponsored by the VA. Requests involving non-VA funded development are also reviewed to identify products or techniques that may meet specific VA needs in one of the designated special emphasis areas: Prosthetics/Amputations/ Orthotics; Spinal Cord Injury and Related Neurological Disorders; and Communication, Sensory, and Cognitive Aids, with aging and rehab outcomes crossing all three specialties.

The TTS is responsible for the design and management of a systematic process to validate proven rehab R&D findings and to transfer the successful outcomes into clinical use, product manufacture, and commercial availability. The ultimate goal is for timely transition of prototypes into commercially viable products and techniques that benefit veterans and non-veterans with disabilities. This process partners and coordinates the developer, a manufacturer, VA Headquarters, and clinical test sites.

Once the research idea/concept has moved into development, the outcome is usually a working prototype, which then completes successful laboratory and limited clinical trials prior to entering the technology transfer process.

The R&D principle investigator next submits a Request For Evaluation (RFE) to the TTS. The RFE elicits specific information that is used to review the appropriateness and readiness of the development as a TTS project. A RFE peer review then confirms VA's need, interest, and readiness of the developed product or technique for evaluation and clinical use. The following selection criteria are used for the review: 1) VA level of need/interest; 2)fitness for use; 3) manufacturable/pre-commercial; and 4) marketable.

Once the RFE peer review is complete and responses are positive, the TTS formulates and submits a recommended plan of action, including budget support, to the Director, Rehab R&D Service. Approval at this level commences the manufacture and evaluation phases, after which TTS prepares the final report with specific recommendations for commercial availability.

Scientific and Technical Publications Section

Jon S. Peters, Acting Program Manager

The Scientific and Technical Publications Section (STPS) disseminates the results of VA and non-VA scientific and engineering projects among researchers, engineers, clinicians, and consumers in the United States and throughout the world. STPS distributes research, development, and clinical information through print and electronic media, including publication of the peer-reviewed *Journal of Rehabilitation and Development (JRRD), Rehabilitation R&D Progress Reports,* and clinical supplements to JRRD. STPS also has an Information Resource Unit with a visual information specialist and a scientific and technical photographer.

Under the Office of Research and Development, Rehab R&D Service has a Research and Development Center or Unit in each of the following locations:

Center of Excellence in Geriatric Rehabilitation

Rehabilitation Research and Development Center, VA Medical Center Atlanta, Decatur, GA 30033

Joseph G. Ouslander, MD, Director

The Atlanta Center is charged with improving the function, independence, and quality of life of Veterans aging with disabilities by working to understand the mechanisms underlying those impairments and applying this understanding to the design, testing, and evaluation of creative rehabilitative interventions.

In the fall of 1996, Joseph G. Ouslander, MD, was appointed Director of the Center. Dr. Ouslander is an internationally recognized researcher in long-term care with experience in developing and managing research centers that focus on functionally disabled older adults.

A graduate of Johns Hopkins with his MD from Case Western Reserve, Dr. Ouslander brings a wealth of general and specialized medical expertise to the Center. He is board-certified in both Internal and Geriatric medicine, in addition to being a Certified Medical Director. He sits on the editorial boards of several journals, as well as reviewing manuscripts for several more, including *JAMA* and *The New England Journal of Medicine.*

As active in teaching as in the practice of medicine, Dr. Ouslander has been on the faculties of Johns Hopkins and UCLA; he presently is Professor of Medicine at the Emory University School of Medicine, where he is Director of the Division of Geriatric Medicine and Gerontology and also Chief of Medicine at the Wesley Woods Geriatric Center. His publications of journal articles, book chapters, and monographs number in the hundreds, as do his presentations and lectures at scientific and medical conventions.

Though a Rehabilitation Research Unit has been in existence at the Atlanta VA since 1982, we were officially designated a VA Rehabilitation Research and Development Center by the 5-year plan of 1989. Despite an initial lack of space, equipment, and (for nearly 4 years) a permanent Director, the Center has made major contributions to R&D and to the care of aging Veterans with physical, sensory, and cognitive disabilities. We now have 11,000 square feet of newly renovated contiguous office and laboratory space in the main Medical Center tower and an additional 2,100 square feet of laboratory in the new clinical building.

We direct our research toward understanding the mechanisms underlying the disabilities associated with age and we apply this understanding to the design, testing, and evaluation of creative rehabilitative interventions in three areas: vision, environment and behavior, and physical performance and exercise. We also indertake projects that highlight the interactions among these areas. The Center is structured according to those three areas: supporting the researchers in each are the administrative support and the core services whose functions cut across the research and training programs: statistical and data management and dissemination of information.

The senior investigators and support group leaders meet monthly as an internal steering group to review both developmental and major research proposals, provide feedback to the investigators, make decisions on which developmental research projects should be supported, and advise the Director on major administrative issues. We benefit from a National Advisory Group of recognized experts in areas relevant to our research that meet with key Center investigators for 2 days yearly to review our research activities and suggest future directions. We also receive annual guidance from a Consumer Advisory Group of representatives from major consumer organizations that meets with investigators and staff on research directions and dissemination activities.

In addition to major research projects, a developmental research program will utilize Center core support for two projects per budget year in each of the major research areas, and one or two rehabilitation engineering projects in conjunction with a collaborative program among medical and engineering scientists at Emory and Georgia

Tech. This program will promote the Center's growth and success by developing preliminary data critical for major research proposals; fostering interdisciplinary research, involving investigators from affiliated institutions, providing opportunities for graduate students and junior investigators, and developing research proposals for submission to the VA, NIH, and other funding sources. We have thus far dedicated $120,000 to the support of eight developmental projects during this budget year.

We work with our major university affiliates to identify promising graduate students and to involve them in Center research through graduate research assistanceships (GRAs) or other mechanisms. We network nationally to identify promising postdoctoral and junior investigators interested in our research areas. Students involved in Center-based training activities will be enrolled in appropriate programs at Emory (neuroscience, physical therapy, clinical psychology), Georgia Tech (biomechanical and electrical engineering, architecture), and Georgia State (kinesiology and health, gerontology), leading to MS, PhD, or MD degrees. Additionally, Emory has physician residents and fellows in Rehab Medicine and Geriatrics who can be involved in Center research. All trainees will be expected to actively participate and periodically present at the Center's research seminar/journal club. The Center has budgeted $40,000 this year to support trainees: presently, we are working with one graduate student from Georgia State and one graduate and two undergraduate students from Georgia Tech.

While our primary university affiliation historically has been with nearby Emory University, we are strengthening our relationships with Georgia Tech and Georgia State. With an enrollment of almost 12,000 students and over 2000 full-time faculty and professional researchers, Georgia Tech is the South's largest industrial and engineering research agency. Georgia State University is one of four research universities in the University System of Georgia, providing undergraduate and graduate education to 24,000 students through six colleges offering 46 different undergraduate majors, 23 master's programs, and 14 doctoral degree programs.

The gold standard of research is publication, and we are proud that so much of our research has been recognized by our peers in the field.

Center of Excellence for Functional Electrical Stimulation

A consortium of the Cleveland VA Medical Center, Case Western Reserve University, MetroHealth Medical Center, and Edison BioTechnology Center

P. Hunter Peckham, PhD, Director

The Functional Electrical Stimulation (FES) Center of Excellence is part of an internationally recognized consortium known as the Cleveland FES Center. It consists of the Cleveland VA Medical Center, Case Western Reserve University, Metro Health Medical Center, and Edison BioTechnology Center.

A Professor of Biomedical Engineering and Orthopaedics at Case Western Reserve University (CWRU) and Director of the Rehabilitation Engineering Center in the Department of Orthopaedics of MetroHealth Medical Center (MHMC), P. Hunter Peckham, PhD, received his BS in mechanical engineering from Clarkson College of Technology, Potsdam, NY, and the MS and PhD in biomedical engineering from CWRU. He serves as Associate Editor of the *IEEE Transactions on Rehabilitation Engineering*, and, in 1996/1997, chaired the National Advisory Board to the National Center for Medical Rehabilitation Research of the National Institutes of Health. His interests include rehabilitation engineering in spinal cord injury (SCI), neural prostheses, and functional electrical stimulation (FES).

Loss of central nervous system function is a major cause of disability, and presents substantial individual and family burdens as well as major economic consequences. While conventional rehabilitation maximizes the retained function of the disabled individual, few interventions increase control of the paralyzed or paretic functions. One technique that does enhance function is FES, and this technique has its roots in Cleveland, where many of its first accomplishments have been achieved. FES has made the transition from the bench to the bedside, with individuals who have lost function in their hands able to manipulate objects, who have lost function in their legs able to stand and walk, and who have lost control of their bowel and bladder regain active control.

In 1991, the FES Center was founded in Cleveland to capitalize on this work, fostering a close relationship across institutions to integrate related projects and investigators and provide resources available uniquely through resources of each institution. Recent significant accomplishments of the Center include the FDA approval of a hand grasp system and commencement of clinical trials of an advanced bladder/bowel management system. Current continuing key areas of activity include clinical development of implantable command/control systems for bilateral hand grasp and implantable systems for transfer and mobility, as well as research activities in unassisted standing, upper arm control, and evaluation of FES therapies in the treatment of stroke-related impairments.

The consortium basis of the Center provides the core support for the program, the working framework for the 20 principal investigators, and various specialized laboratory facilities. Investigators are responsible for developing their own funding outside of the core funding provided by the VA. Personnel are affiliated with the Center through a number of mechanisms: full and part-time term appointments, joint appointments with the consortium partners, and inter-agency personnel agreements. This leads to a multiinstitutional mechanism for conducting the objectives of the Center and for leveraging the grant resources that each of the member institutions has to provide.

In FY97, the Center's consortium partners generated approximately $2.6 million in funding from foundations and federal agencies other than the VA for more than 20 projects. With core funding of $880,000 and 6 VA Merit Review projects totaling approximately $1.3 million, the Center utilized approximately $4.8 million for the year.

The core funding resources are used primarily to support the infrastructure of the research consortium. Additional support is provided for assisting fellows and young investigators in establishing careers in the field and creating pathways for their own funding support: 25 individuals are so supported for at least part of FY98, amounting to a total of approximately 11 FTE. Core plus project funding provides support for 50 individuals, for a total of approximately 46 FTE.

During the past year, the Center has carried out the clinical implementation of fully implanted systems for hand-arm control in two persons with C5/6 SCI. They have obtained the ability to regain control of grasp and release and elbow extension with a fully implanted neuroprosthesis. This is the first implementation of a system including both stimulator and the control sensor. We have implanted systems for standing-transfer and stepping for two persons with incomplete tetraplegia for transfer assist and two persons with paraplegia for walking. The first system employs our 8-channel implant, while the second uses two devices to activate 8 muscles per leg. We have implemented with a percutaneous system in eight persons with stroke to reduce shoulder subluxation and accompanying dysfunction and pain. Preliminary results support the efficacy of this treatment modality. Research is underway in two parallel studies to investigate use of FES of lumbo-sacral nerves to control urination and defecation in persons with SCI. Implants have been performed on 16 persons, confirming the efficacy of this technique. We have developed a smaller, portable external control unit, primarily for use in lower extremity mobility studies: this controller allows user control of two implanted stimulators powered and controlled by radio frequency. Transfer to a manufacturer is underway.

Since 1989, the FES Center has disseminated research information through the FES Information Center, responding to more than 6,000 inquiries from individuals around the world interested in how FES can help people with disabilities. In FY97, just over 1,000 inquiries were received, representing a 31% increase over the previous fiscal year and demonstrating significant growth over recent years.

Center publications include the FES Update newsletter (circulation 8,000) and the FES Resource Guide, a 200 page sourcebook for individuals with SCI or multiple sclerosis. In 1996, we established an Internet presence with a pilot web site (http://feswww.fes.cwru.edu) that has logged as many as 1,000 visitors a month. It features a staff directory, project descriptions, our FES Update newsletter and selected bibliographies.

During the year, Center members published 20 peer-reviewed articles and book chapters, with an additional 18 in press. They gave 65 presentations at national and international meetings, and attended 17 scientific meetings. In addition to their peer-reviewed professional work, they addressed the lay audience in 71 print articles and 12 broadcast presentations.

National Center of Excellence on Healthy Aging with Disabilities

Rehabilitation Research and Development Service, Houston VA Medical Center

Arthur M. Sherwood, PE, PhD, Director

This new Center will conduct research directed to the elimination of preventable secondary problems and the reduction of risks for all secondary conditions related to disabilities. Researchers will seek to promote early initiation of treatment, to develop more holistic intervention programs, to educate veterans and family caregivers, and to develop better assistive devices, including mobility aids.

An author of more than 45 scientific papers, 18 book chapters, and 105 abstracts of presentations, Arthur M. Sherwood, PE, PhD, is a biomedical engineer who has worked in the area of assessment of motor and sensory function through use of surface EMG and evoked potentials for more than a quarter century. His work in recent years has focused upon the development of surface EMG techniques for quantitative assessment of motor control problems in severe spinal cord injury (SCI), including tracing residual motor control in paralysis and studies of spasticity.

The Houston Center is new; approved in May 1997, it began operations in October 1997. Approximately 40 area professionals have indicated an interest in working with the Center, and 9 projects from these individuals are in process of initiation, approval, or funding. Our focus is on collaborative, interdisciplinary research toward new clinical interventions to decrease the number of secondary complications in aging disabled veterans. Enhanced research skills of Center personnel will enable the Center to address an increasing number of important clinical problems. Education programs aimed at the consumer, family caregiver, and general public will convey strategies leading to more healthful lifestyles, increased independence, and a consequent increased quality of life for those veterans.

The majority of the Center staff are members of the faculty of the Department of Physical Medicine and Rehabilitation of Baylor College of Medicine. Services of those not directly employed by the DVA have been secured through a sub-contract negotiated with Baylor College of Medicine. This contract, totaling nearly $200,000, covers full or partial support for seven faculty and one staff individual. The Center's investigators have a broad array of expertise and research interests, including fitness, nutrition, sexual function and mobility, and motor control. Serving their studies, we have motor and sensory laboratories, prosthetics shops, and a variety of biological laboratories. We are developing a database to capture information from veterans seen through the clinics and admitted to the services for inpatient care. This database will have two basic components: 1) a registry of all persons over 50 years of age with disabling conditions, 2) a sample database containing detailed information on a sample of persons over 50 years of age admitted for inpatient services. By collecting basic demographic, social, medical and disability data on every person seen by the three services in the Center, we shall be better able to identify specific areas for further research and to provide subject information for research studies developed by the Center.

As the Center did not establish operation until fall 1997, there is no recent work to report. However, the investigators now active in Center programs published widely during the past year.

Center of Excellence on Mobility

VA Palo Alto Health Care System Rehabilitation R&D Center

Felix E. Zajac, PhD, Director

This Center's task is to increase the independence and improve the quality of life of persons with neurologic and orthopedic impairments through the development of innovative treatments and technical devices.

Recipient of many awards in engineering and biomechanics, Felix E. Zajac, PhD, serves in a number of advisory capacities to the National Institutes of Health; he is a member of the Scientific Advisory Board of the Paralyzed Veterans of America and a Founding Fellow of the American Institute of Medical and Biological Engineering.

Dr. Zajak is currently a Professor of Mechanical Engineering in both the Biomechanical Engineering Division (School of Engineering), and the Department of Functional Restoration (School of Medicine) of Stanford University; he has been the Director of the Rehabilitation R&D Center of the Veterans Affairs Palo Alto Healthcare System since 1979. He holds the BEE from Rensselaer Polytechnic Institute and both the MS in Electrical Engineering and the PhD in Neurosciences from Stanford. Building on past work on the properties of motor units, Dr. Zajac currently studies the dynamics, muscular coordination, and sensory control of multiarticular motor tasks, with application to the rehabilitation of persons with neurologic and orthopaedic impairments.

The Center he directs, the VA Palo Alto Rehabilitation R&D Center of Excellence on Mobility, is dedicated to developing clinical treatments and technological devices for physically disabled veterans and others, in order to increase their independence and improve their quality of life. Focusing on the improvement of mobility in persons with neurologic or orthopaedic impairments, the Center's primary emphasis is on restoring and enhancing muscle coordination in persons who have had a stroke or have sustained a spinal cord injury (SCI), and on restoring and maintaining musculo-skeletal function and integrity in persons with osteoporosis, arthritis, or SCI. We also perform basic research to better understand the way in which the nervous system coordinates muscles during complex motor tasks, and the way in which bone grows, maintains, and regenerates itself.

The Core budget is allocated to salaries, startup projects, and common resource equipment of the Center, and amounts to $1.36 million for FY97. In the same year, the Center received nearly $1.22 million in VA Rehabilitation R&D Merit Review project monies and another $54,194 for projects under the VA Medical Merit Review. We secured an additional $634,000 from non-VA sources, including the National Institutes of Health, The Paralyzed Veterans of America, The Whitaker Foundation, and others.

The Center has a long-standing affiliation with the Stanford University, particularly with the Departments of Mechanical Engineering (and its new Biomechanical Engineering Division), and Functional Restoration. In fact, all Center investigators have faculty/lecturer appointments in these departments. Graduate and undergraduate Stanford students are routinely involved in Center projects. Investigators also regularly collaborate with outside institutions in areas of relevance to the Center mission.

Center investigators are currently doing basic research in such areas as, the effect of exercise on the ambulation of stroke patients, and mechanically assisted upper limb movement for them; the noninvasive investigations of musculoskeletal function and the assessment of that function by automated evaluation of electromyograms; work in grafting of peripheral nerves, and comparison of synthetic and autologous connective tissue grafts; the reliability and validity of accelerometric gait, and the functional restoration of grasp in quadriplegia; the basic mechanics of function, and the feasibility of video-based assessment of that function. They are also studying the skeletal changes after spinal cord injury and cast immobilization, the the theory and modeling of bone adaptation during disuse and recovery, and the modeling of tendon development, adaption, and regeneration; the mechanical regulation of peri-prosthetic tissue differentiation, computer simulation analysis of coordination deficits post-stroke, and mechanical loading effects on cartilage repair and regeneration. At the most basic level, they are working on models of human postural coordination, and the intermuscular coordination of mammalian movement.

In the area of applied technology, Center researchers are investigating obstacle avoidance training with computer-simulated environments, the development of an assistive robot for effective health care delivery, and differential pressure walking assistance.

During the past year, they have published numerous works, in additions to presentations and lectures to professional organizations.

Portland RR&D Center for Rehabilitative Auditory Research

Portland VA Rehabilitation Research and Development Center
Stephen A. Fausti, PhD, Director

This new Center for Rehabilitative Auditory Research will work to alleviate the communicative, social, and economic problems resulting from auditory system impairment by focussing on basic research and development, the training of investigators, and the dissemination of results useful to clinicians who assess and treat veterans with hearing loss and tinnitus.

Chief of Audiology at the Portland VA Medical Center for 25 years, Dr. Fausti has extensive experience as a researcher, clinician, and academician. He is Professor of Audiology in the Department of Otolaryngology of Oregon Health Sciences University, and Adjunct Professor of Audiology at Portland State, both of Portland, and an Editorial Associate of the Journal of the American Academy of Audiology.

His work in various phases of high-frequency audition and ototoxicity monitoring has also received continuous Medical and Rehabilitation R&D Merit Review funding since 1977. He and his group produced the first papers describing the validity and reliability of high-frequency (>8000 Hz) hearing thresholds and subsequently their efficacy in monitoring hearing for early detection of ototoxicity. Data from these studies formed the basis of national guidelines for a standardized ototoxicity monitoring protocol by the American Speech-Language-Hearing Association. More recently, his program launched investigations into the auditory brainstem response (ABR) as an objective measure of high-frequency auditory function for evaluating patients who cannot provide reliable results to behavioral evaluation methods. In the area of tinnitus his work has led to the development and investigation of an automated tinnitus evaluation system, which obtains reliable measures of hearing thresholds, tinnitus pitch, and tinnitus loudness. This research has involved multiple participating sites from 1988 onward: Dr. Fausti has a well-developed expertise in overseeing large multisite prospective studies.

Dr. Fausti's experience and network of collaborative investigators made Portland an ideal site for the new Center, begun October 1997 to alleviate the communicative, social, and economic problems resulting from sensorineural hearing loss (SNHL) and tinnitus.

Rehabilitation of persons with SNHL and efficacious alleviation of tinnitus, especially prevalent disorders among veterans because of their history of noise exposure compounded by aging, are the focus of current and future research efforts.

Speech perception is dependent upon complex functional processes that occur within the peripheral and central auditory nervous system. Auditory disorders in the peripheral auditory system manifest in numerous ways beyond the obvious reduction in auditory sensitivity. For example, impairments in frequency and temporal resolution, loudness growth, sound localization and speech recognition are reportedly impaired by SNHL, and the relationships among these various changes are unclear and their combined effect on speech recognition still speculative.

While developments in programmable hearing aids are impressive, technology has outpaced our knowledge of the effect of SNHL on the auditory system and speech recognition. Today's tests of speech recognition are poor predictors of speech perception in real life environments. Center will address this problem through a multidisciplinary approach, including some basic research clarifying effects of sensorineural loss on frequency selectivity, temporal resolution, and localization; and applied research designed to provide new methods for assessing speech recognition tests. Other areas of inquiry are the development of hearing aids and assistive devices, which will aid veterans with multisensory disabilities (hearing loss and blindness). Rehabilitative inquiry aims at correcting functional impairments. Identification and correction of impairments permits specific targeting of rehabilitation efforts.

The Center is currently affiliated with Portland State University, Oregon State University, and the Oregon Health Sciences University (OHSU), including the Departments of Otolaryngology and Neurology and the Oregon Hearing Research Center at the latter. We work closely with the VA Medical Centers at West Los Angeles, CA, Nashville, TN and Albuquerque, NM to conduct jointly sponsored clinical trials with the National Institutes of Health, NIDCD, and the Lexington Center for the Deaf.

Grant support for FY97 consists of $474,000 in direct funding from the VA (both Medical and Rehabilitation R&D) and the NIDCD.

In addition to presentations and courses conducted at meetings of professional associations, Center researchers publish widely.

Research and Development Center for Amputation, Prosthetics, Limb Loss Prevention

VA Puget Sound Healthcare Center, Seattle, WA
Bruce Sangeorzan, MD, Director

This Center was developed to study the prevention of amputation, improvement of lower limb prosthetics, and measurement of outcomes for these patients; and to establish a collaboration between the VA, Departments of Orthopedics and Rehabilitation Medicine at the

University of Washington, and the Prosthetics Research Study Group.

A National Merit Scholar, Bruce J. Sangeorzan, MD, holds the BS in biology from the University of Michigan and the MD from Wayne State. In addition to directing the Center, he is active in both his medical practice and teaching: he is Chief of Orthopedics at the Seattle VA Medical Center and Professor of Orthopaedic Surgery at the University of Washington. He also serves as an Associate Editor for two peer-reviewed journals and reviews manuscripts for four more. Author of some 50 articles and chapters in professional journals and books, he has delivered 125 invited lectures on orthopedics and presented original work to professional meetings across the U.S.

Dr. Sangeorzan oversees a Center that continues the strong tradition of interdisciplinary amputation research dating back to Dr. Ernest Burgess' initiation of the team approach to prosthetics and amputation in the 1960s that, by the 80s, had grown into the Special Teams for Amputation Mobility Prosthetic/Orthotic (STAMP) program. One of the first to routinely test aging veterans for diabetes (the leading cause of nontraumatic lower-limb loss) Puget Sound has long been a magnet for referrals of veterans with limb-at-risk and amputation-related problems.

The Center's overall goal is to establish a community of clinical and basic scientists to pursue research objectives in the area of lower limb prosthetics and amputation. We shall seek ways to improve the possibility of preservation of the lower limb, working to make more effective decisions with regard to the surgical issue of amputation versus salvage. Since level is a key factor in ambulation and independence, we shall study the effect of location of amputation and its relationship to wound healing and postamputation function and evaluate the mechanical function of prosthetics to allow the optimal design for each individual, continuing our efforts to improve the process of fitting, design, and function of current prostheses.

Overall, we shall measure functional outcomes of the persons we treat, tracking the results of innovation in terms of their positive impact on the lives of veterans, and we shall continue to disseminate the information we discover.

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The 1st Annual Meeting of the VA Rehabilitation Research and Development Service, "Enabling Veterans: Meeting the Challenge of Rehabilitation in the Next Millenium," will be held Thursday, October 1 through Saturday, October 3, 1998 at the Westin City Center Hotel, Washington, DC. The purpose of this meeting is to create a knowledge base of the current status of research, and to maximize interpersonal exchange among investigators. The scientific program features poster presentations; an exhibit area will highlight the research programs of the VA RR&D Centers.

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